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Health Tech Programme

Diagnostics Advisory Committee

HTE10065 Algorithms applied to spirometry to support the diagnosis of lung conditions in primary care and community diagnostic centres

committee 1 discussion

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Link to SCM/Experts register for topic:	https://www.nice.org.uk/guidance/indevelopment/gid-hte10065/documents

The following documents are made available to the Committee:

1. Cover sheet
2. External assessment report overview (ARO)
3. External assessment report (EAR)
4. Stakeholder comments and EAG responses on the EAR and model
5. Register of interests

Early Use Assessment

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

GID-HTE10065

Assessment report overview

This overview summarises key information from the assessment and sets out points for discussion in the committee meeting. It should be read together with the final scope and the external assessment report. A list of abbreviations used in this overview is in appendix A.

1. The technologies

This assessment included 6 technologies that use algorithms to support the diagnosis of lung conditions through means of quality assessment or interpretation of spirometry measurements (see Table 1). Four of the included technologies are software that do not come with hardware, but require hardware to complete testing (ArtiQ.Spiro, EasyOne Connect, LungHealth and MIR Spiro). Two technologies include both hardware (e.g. spirometer) and software elements (NuvoAir, GoSpiro). Technologies can be broadly classified into two types of algorithms: AI-derived algorithms and rules-based algorithms only. See section 5 of the final scope and Table 2 in the external assessment report (EAR) for additional details about the included technologies.

Table 1: Interventions

Technology (company)	CE mark	Population	Type of algorithm	Setting	Component parts
ArtiQ.Spiro [ArtiQ.PFT] (Clario)	IIa	5-96 years	AI and rules-based (ATS/ERS**)	Clinic	Software that is compatible with specified spirometers.
LungHealth (LungHealth)	I	18+ years for COPD, 12 years + for asthma	AI and rules-based (NICE/ BTS/ GOLD/SIGN***)	Clinic	Software only. Requires input of spirometry results (performed using any spirometry hardware).
*MIR Spiro (Medical International Research, MIR)	IIa	5 years +	Rules-based (ATS/ERS)	Clinic	Software that is compatible with specified spirometers.
*EasyOne Connect (NDD)	IIa	4 years +	Rules-based (ATS/ERS)	Clinic	Software that is compatible with specified spirometers.
GoSpiro (Monitored Therapeutics)	IIa	5 years +	AI and rules-based (ATS/ERS)	Clinic	Software and hardware (e.g. spirometer) components provided
NuvoAir (NuvoAir) [Air Next]	IIa	5 years +	AI (interpretation of spirometry results) and rules-based (ATS 2019)	Home-based	Software and hardware (e.g. spirometer) components provided

*Note: descriptions of MIR Spiro and EasyOne Connect have been written from information that is available in the public domain

** ATS/ERS: American Thoracic Society (ATS) and European Respiratory Society (ERS)

*** NICE/BTS/GOLD/SIGN: NICE, British Thoracic Society (BTS), Global Initiative for Chronic Obstructive Lung Disease (GOLD), Scottish Intercollegiate Guidelines Network (SIGN)

2. The condition

Respiratory disease affects 1 in 5 people and is the third biggest cause of death in England. Some lung diseases are classified as being restrictive, where there is a small lung volume that restricts a person's ability to inhale air. Idiopathic pulmonary fibrosis is an example of a restrictive lung disease. Other lung conditions may be classified as 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.

Asthma is a chronic respiratory condition usually associated with airway inflammation and hyper-responsiveness. 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). People living with asthma commonly experience exacerbations, which are periods of worsening of symptoms. 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. 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. Current practice

People with suspected lung conditions should have a structured clinical assessment to understand their clinical history, including their symptoms and risk factors. An initial assessment is carried out by GP. Diagnosis should not be based on clinical assessment alone because some symptoms are not specific to just one lung condition. Objective tests should be performed to

confirm a diagnosis following clinical assessment, to help clinicians differentiate between obstructive and restrictive lung conditions.

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 in community diagnostic centres depending on resource availability but may otherwise be performed in secondary care.

Spirometry is another objective test and is the most commonly performed pulmonary function test for the diagnosis of lung conditions. 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.

Spirometry may be performed in primary care (where the measurement is taken by a nurse/healthcare assistant with GP interpretation of results), in a community diagnostic centre (followed by GP referral with results interpreted in the community diagnostic centre or sent back to be reviewed by GP) or in secondary care setting (if access to resources in primary care/community diagnostic centre or diagnostic inaccuracy requires specialist input).

Bronchodilator reversibility testing is recommended to distinguish between a diagnosis of COPD or asthma using the help of American Thoracic Society and European Respiratory Society (ATS/ERS) guidance. There are NICE guidelines specific to the diagnostic pathways for common lung conditions including asthma (for children and adults), COPD and idiopathic pulmonary fibrosis.

4. Unmet need

There are a significant number of people living with a respiratory disease who have not received a formal diagnosis or undergone investigation, with an estimated backlog of 200–250 patients per 500,000 people awaiting diagnostic testing. Algorithms to support spirometry may give faster access to objective diagnostic testing for suspected lung conditions, for example by enabling less-experienced staff to perform and interpret spirometry. There are a considerable number of people for whom the given diagnosis is incorrect, who may go onto receive unhelpful (and potentially harmful) treatment, or miss out on treatment all together if the diagnosis is missed. Algorithm support may improve the quality of spirometry and accuracy of the subsequent diagnosis. This could potentially reduce the number of patients referred to secondary care due to doubts in diagnosis or as a result of exacerbations because of misdiagnosis or incorrect or lack of treatment. Further details, including descriptions of the interventions, comparator, care pathway and outcomes, are in the final scope.

5. Clinical effectiveness

The EAG did searches to identify relevant published clinical evidence. The search and selection methods are in section 4 of the external assessment report (EAR). Section 5 of the EAR gives results of the included publications for each outcome, for each of the interventions.

5.1 Overview of key studies

A total of 30 studies were included in the review. Eight of these studies (in 3 technologies) looked at exclusively undiagnosed populations of patients, and 22 studies included populations of patients who already had an existing diagnosis (in line with section 2.1 of the EAG's protocol). Across the included studies, 11 were on ArtiQ.Spiro, 1 on GoSpiro, 9 on LungHealth, 3 on MIR Spiro, and 6 on NuvoAir. No relevant evidence was identified by the EAG (or submitted by the company) for the EasyOne Connect technology. The EAG noted a general lack of peer-reviewed sources of evidence for most technologies, with the evidence including abstracts, posters, editorials, pre-

print publications and information provided in confidence. See Table 3 in the EAR for the study characteristics of included studies.

5.2 Diagnostic accuracy of initial diagnosis

ArtiQ.Spiro

Mixed adult population

Doe et al. (2025a) reported results from a UK RCT (SPIRO-AID trial, NCT05933694) where 133 primary care clinicians who refer for, perform, or interpret spirometry were randomised to review 50 retrospective spirometry records with or without ArtiQ.Spiro AI support. Records included a sample of 40% COPD, 20% normal spirometry, 10% asthma, 10% ILD, 10% other obstructive, 10% other disease or unidentifiable category. The reference diagnosis standard was a diagnosis by two respiratory physiologists without access to the AI software reports. A correct case is where the preferred diagnosis (disease category with the most likely diagnosis) matches the reference final diagnosis. Authors report that the addition of ArtiQ.Spiro led to improvements in preferred diagnosis prediction performance, with a mean of 58.7% in the intervention group and 49.7% in the control group (p=0.001). Similar mean differences were seen regardless of role (GP or non-GP) or inclusion on the National Spirometry Register.

Maes et al. (2024) reported that 6 GPs agreed with the diagnosis proposed by ArtiQ.Spiro in 77% of cases.

People with suspected COPD

Using data from the SPIRO-AID trial, the EAG note that sensitivity (based on spirometry records of 20 people with COPD) was higher for clinicians using ArtiQ.Spiro ([redacted]%) than those not using the technology ([redacted]%), although there was little difference in specificity between arms, with [redacted]% compared with [redacted]% respectively. See Appendix D4 in the EAR.

The UK retrospective, blinded, diagnostic validation study by Sunjaya et al. (2025) reported that for 543 patients diagnosed with COPD, ArtiQ.Spiro had a

preferred diagnosis sensitivity of 84.0% (95% confidence interval, CI 80.6 to 87.0), specificity of 86.8% (95% CI 83.8 to 89.5), and accuracy of 85.4% (95% CI 83.2 to 87.5) compared with the reference diagnosis (consensus of experts with access to primary and secondary care medical notes and results of relevant investigations). When applying the differential diagnosis (top two categories with highest probability scores) from ArtiQ.Spiro the sensitivity increased to 90.6% (95%CI 87.8 to 92.9) and the specificity decreased to 75.6% (95% CI 71.9 to 79.1). Agreement between ArtiQ.Spiro and a reference diagnosis had an overall Cohen's Kappa agreement coefficient of 0.477, and the most common misclassification for COPD patients was asthma (8.29%) followed by ILD (5.16%), with 1.47% being classed as normal. See Table 5 of the EAR.

An abstract (Polaris, 2025) used spirometry data from a cohort of 248 patients attending a COPD diagnostic pathway. There were high levels of agreement between 'normal' AI interpretation and 'normal' clinician-reported spirometry results and diagnoses (negative predictive value = 0.942), assumed to refer to there being no sign of COPD or other lung conditions. No information was given on agreement of COPD diagnoses between AI interpretation and reference diagnosis.

Adults with suspected asthma

The EAG used the data for the SPIRO-AID trial team to calculate the sensitivity and specificity, based on 6 of 50 patients in the dataset diagnosed with asthma. Sensitivity was higher for clinicians using ArtiQ.Spiro ([redacted]%) than those not using the technology ([redacted]%), although there was little difference in specificity between arms, with [redacted]% compared with [redacted]% respectively.

Sunjaya et al. (2025) reported that for 107 patients diagnosed with asthma, ArtiQ.Spiro had a sensitivity of 55.1% (95% CI 45.2 to 64.8), specificity of 86.9% (95% CI 84.6 to 88.9), and accuracy of 83.8% (95% CI 81.5 to 85.9). Most common misclassifications by ArtiQ.Spiro for asthma patients was COPD (16.82%) followed by ILD (14.02%), with 5.61% of diagnoses classed

as being normal. The EAG note that diagnostic accuracy performance was better for identifying COPD than asthma across the included evidence.

Adults with suspected ILD

Sunjaya et al. (2025) reported that of 249 patients diagnosed with ILD (reference diagnosis of expert consensus), ArtiQ.Spiro had a sensitivity of 75.1% (95% CI 69.3 to 80.3), specificity of 85.9% (95% CI 83.4 to 88.1), and accuracy of 83.5% (95% CI 81.2 to 85.6). Most common misclassifications by ArtiQ.Spiro for ILD patients was asthma or classed as normal with 7.63% for each respectively.

The UK retrospective cohort study by Ray et al. (2022) included data from 109 patients who had ILD as a cause of death and who had spirometry performed within seven years prior to their death, with no diagnosis of ILD on the day of the spirometry test. ArtiQ software noted that ILD was the highest probable disease detected in 26.6% (29 of 109) patients, including where spirometry parameters were within normal limits of the ATS/ERS 2005 interpretation guidelines.

The EAG rated this outcome as being GREEN in their evidence gap analysis for ArtiQ.Spiro (see Table 38 in the EAR).

LungHealth

One study (Chakrabarti et al. 2025d) reported how many people were given a diagnosis of COPD using LungHealth, and eight studies reported the proportion of people who had their diagnosis changed following LungHealth review (ranging between 14.6% and 29.2%). All studies were non-comparative and lack a reference standard to confirm the accuracy of diagnosis. See table 12 in the EAR. Given this evidence is from non-comparative studies and largely in a diagnosed population, the EAG rated this outcome as being AMBER in their evidence gap analysis for LungHealth (see Table 38 in the EAR).

MIR Spiro

An RCT, Lusuardi et al. (2006), done in Italy compared primary care diagnosis by a GP with and without the use of the MIR Spirobank Office spirometer (see Table 15 in the EAR). The reference standard was pulmonary specialists in secondary care. The diagnostic concordance per protocol was 78.6%, and the diagnostic concordance in the intention-to-treat protocol was 57.9%. The level of agreement between GPs and specialists was not found to be significantly different. Given this evidence is from a single non-UK study (likely using an older model of technology) the EAG rated this outcome as being AMBER in their evidence gap analysis for MIR Spiro (see Table 38 in the EAR).

NuvoAir

Of four studies reporting on accuracy of the initial asthma diagnosis (Tuli, 2025; Gray, 2026; Parrott et al., 2023; Robshaw, 2025), no comparative evidence was identified that reported the accuracy of the algorithm interpretation against standard care. See Table 19 in the EAR.

A study submitted as academic in confidence by the company (Tuli, 2025), included [redacted]

In a study of 40 adults on a 12-week Asthma Home Programme (following referral for either uncertain diagnosis of asthma or assessment of uncontrolled symptoms), it was reported that 67% received an accurate diagnosis (Parrott et al., 2023).

In a study of 112 adults referred to NuvoAir, 38% patients had diagnosis confirmation (including 14 patients with confirmed asthma), and 5 had their asthma diagnosis changed and were referred back to their GP (Robshaw, 2025).

Given this evidence is from non-comparative studies and largely in a diagnosed population, the EAG rated this outcome as being AMBER in their evidence gap analysis for NuvoAir (see Table 38 in the EAR).

EasyOne Connect and GoSpiro

No studies were identified that reported this outcome for these technologies. The EAG rated this outcome as being RED (see Table 38 in the EAR).

5.3 Accuracy of interpretation of spirometry

ArtiQ.Spiro

Doe et al. (2025a) reported that for 67 clinicians who had access to ArtiQ.Spiro, correct spirometry pattern interpretation was made in 64.9% cases compared with 65.8% for 66 clinicians who did not use the technology. Wide confidence intervals do not suggest a significant difference between study arms. The EAG rated this outcome as being AMBER in their evidence gap analysis for ArtiQ.Spiro (see Table 38 in the EAR).

LungHealth

Four UK service evaluations reported spirometry pattern interpretation using LungHealth (see table 13 in the EAR). No comparative evidence was available to determine the accuracy of the spirometry pattern interpretation. The EAG rated this outcome as being AMBER in their evidence gap analysis for LungHealth (see Table 38 in the EAR).

MIR Spiro

Lusuardi et al. (2006) reported proportions of spirometry pattern results (number of patients not reported). The EAG rated this outcome as being AMBER in their evidence gap analysis for MIR Spiro (see Table 38 in the EAR).

5.4 Quality of spirometry performance

ArtiQ.Spiro

Two UK comparative studies (Adams et al. 2024, Doe et al. 2025a) reported that the quality of spirometry performance was improved using ArtiQ.Spiro. The UK RCT by Doe et al. (2025a) reported an increase in the proportion of measurements with correct grading of 5.0% for FEV1 and 10.8% for FVC respectively when the ArtiQ.Spiro technology was used. In the UK service evaluation by Adams et al. (2024), ArtiQ.Spiro agreed with the clinician quality assessment in 94% of 51 spirometry sessions.

The EAG rated this outcome as being GREEN in their evidence gap analysis for ArtiQ.Spiro (see Table 38 in the EAR).

NuvoAir

Five non-comparative studies reported on the quality of spirometry, see table 20 in the EAR. Gray (2026) reported that [redacted] spirometry tests were graded as acceptable (Grade A to C, ATS/ERS guidelines, year not reported). Parrott (2023) reported that 77% of 40 patients' spirometry sessions were Grade A to C, using ATS/ERS 2005 guidelines. Kocks (2023) reported that 59.2% of 140 patients undergoing spirometry had at least 2 acceptable measurements using ATS/ER 2019 guidelines. Robshaw 2024 reported 78% of tests performed by 112 patients were graded acceptable (grading criteria not reported). In an abstract submitted as academic in confidence (Tuli, 2025), [redacted]% of tests performed by [redacted] were graded acceptable (grading criteria not reported). Given this evidence was non-comparative and largely in a diagnosed population, the EAG rated this outcome as being AMBER in their evidence gap analysis for NuvoAir (see Table 38 in the EAR).

5.5 Access to spirometry and the number of tests performed

ArtiQ.Spiro

The UK service evaluation by Hayes et al. (2025b) reported a revised model of spirometry delivery, with testing performed by a Band 3 Respiratory Care and Support Worker supported by AI-assisted interpretation (ArtiQ.Spiro) and supervised by ARTP certified staff. There was an increase in testing capacity of 75 tests per month (see Table 8 in the EAR), and wait times improved (before and after not reported). Full backlog resolution was reportedly projected within 8 months (backlog volume was not quantified)**.** The EAG rated this outcome as being AMBER in their evidence gap analysis for ArtiQ.Spiro (see Table 38 in the EAR).

NuvoAir

The EAG did not identify any comparative evidence reporting the differences in testing capacity from the introduction of NuvoAir, however 5 studies do report the quantity of tests performed during a NuvoAir diagnostic pathway. See table 20 in the EAR. The EAG rated this outcome as being AMBER in their evidence gap analysis for NuvoAir (see Table 38 in the EAR).

5.6 Time to perform and interpret spirometry

ArtiQ.Spiro

Hayes et al. (2025b) reported a reduction of 15 minutes in appointment times (from 60 minutes to 45 minutes), releasing a total of 206 hours of a Band 6 or 7 nurse and 90 hours of a Band 4 (no detail was provided on the time period over which these time savings were observed). Adams et al. (2024) reported that the mean (SD) time for ARTP accredited GPs and nurses to evaluate spirometry results decreased statistically from 10.6 (4.1) mins to 5.6 (5.6) mins ($p<0.001$) by using ArtiQ.Spiro. See table 9 of the EAR. The EAG rated this outcome as being GREEN in their evidence gap analysis for ArtiQ.Spiro (see Table 38 in the EAR).

LungHealth

Angus et al. (2012) reported that patients were given a 45-minute appointment time to allow 15 minutes to perform spirometry and conduct a clinical examination. The EAG assumes that the remaining 30 minutes were for conducting the LungHealth consultation and providing management recommendations. Given there was no comparison to standard care, the EAG rated this outcome as being AMBER in their evidence gap analysis for LungHealth (see Table 38 in the EAR).

MIR Spiro

No comparative evidence was available for the time taken to perform spirometry, however Lusuardi et al. (2006) reported that the mean time (SD) required to instruct patients for spirometry was 5.6 (3.1) minutes and mean spirometry performance time using the MIR Spirobank II was 6.4 (3.5) minutes. The EAG rated this outcome as being AMBER in their evidence gap analysis for MIR Spiro (see Table 38 in the EAR).

5.7 Time-to-diagnosis

ArtiQ.Spiro

A retrospective diagnostic validation study Ray et al. (2022) retrospectively applied ArtiQ algorithm to spirometry measurements of people who had ILD as their cause of death, but had no former diagnosis of ILD. It suggested ILD as a diagnosis in 26.6% patients (29 of 109), implying that ILD could have been diagnosed sooner if ArtiQ had been used to interpret the spirometry. The EAG rated this outcome as being AMBER in their evidence gap analysis for ArtiQ.Spiro (see Table 38 in the EAR).

5.8 Number of referrals to secondary care for a diagnosis

NuvoAir

Two studies (both in a population with suspected or diagnosed asthma) reported proportions of referrals to secondary care for diagnosis, 22% (Parrott et al., 2023) and 26% (Robshaw et al., 2024). See table 21 in the EAR.

The abstract shared in confidence by the company (Gray et al. 2026) did not report any quantitative detail relating to resource use, [redacted]. No further detail, such as the number of clinicians giving feedback or resource use, was provided. The EAG rated this outcome as being AMBER in their evidence gap analysis for NuvoAir (see Table 38 in the EAR).

5.9 Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment

No studies were identified that reported this outcome for any of the included technologies. For all intervention technologies, the EAG rated this outcome as being RED (see Table 38 in the EAR).

5.10 Mortality

No studies were identified that reported this outcome for any of the included technologies. For all intervention technologies, the EAG rated this outcome as being RED (see Table 38 in the EAR).

5.11 Morbidity

No studies were identified that reported this outcome for any of the included technologies. For all intervention technologies, the EAG rated this outcome as being RED (see Table 38 in the EAR).

5.12 Clinician confidence in interpreting spirometry results and making a diagnosis

ArtiQ.Spiro

Four studies reported on clinician confidence using ArtiQ.Spiro, however all measured and reported this outcome differently (see table 10 in the EAR).

Doe et al. (2025a) reported a non-statistically significant increase in primary care clinician (those who refer to, perform or interpret spirometry) confidence in making a diagnosis, FEV1 and FVC technical grading and identification of

spirometry pattern using a 10-point visual analogue scale with (n=67) and without (n=66) ArtiQ.Spiro AI support.

Adams et al. (2024) reported that there was no change in clinician (ARTP-accredited GP or nurse) confidence in spirometry interpretation using a 5-point Likert scale when using ArtiQ.Spiro.

Hayes et al. (2025b) reported survey results (number of participants not reported) from GPs (40%), practice nurses (37%), nurse practitioners or other professionals (11.5% respectively). 40% noted that ArtiQ.Spiro influenced their decision making and 33% found the AI-generated disease suggestion slightly useful, 32% also felt extremely confident or confident with the accuracy of the AI report.

Willaert et al. (2023) reported feedback on the use of AI software (assumed relevant to ArtiQ.Spiro due to author affiliation) for performing and interpreting spirometry. Eight GPs from three Belgian GP practices recognised the need for more objective findings before making a diagnosis or altering therapies and spirometry was noted to be valuable for this with AI-based software felt to be a diagnostic support. Concerns about unfamiliarity with the spirometry procedure and limited time and resources were considered barriers to implementation.

The EAG rated this outcome as being GREEN in their evidence gap analysis for ArtiQ.Spiro (see Table 38 in the EAR).

NuvoAir

Kocks et al. (2023) used questionnaires to gain feedback from 24 practice nurses and 4 GPs, of which 7% agreed that the use of home spirometry improved the diagnostic process and 4% felt that it provided better distinction between asthma and COPD. See table 22 in the EAR. The EAG rated this outcome as being AMBER in their evidence gap analysis for NuvoAir (see Table 38 in the EAR).

5.13 Clinician acceptability, ease of use, experience and satisfaction

ArtiQ.Spiro

Three studies reported on this outcome. See table 11 of the EAR. De Vos et al. (2023) asked GPs in 18 Belgian general practices to rate the usefulness of ArtiQ.Spiro for quality assessment and diagnostic support for people with suspected COPD on a 5-point Likert scale, with results indicating scores of 4.13 and 4.01 respectively. Hayes et al. (2025b) reported survey responses from a mix of clinical staff (number not reported). Authors reported 20% of survey respondents agreed that ArtiQ.Spiro saved them time. Only 17% felt satisfied with the AI service as compared to the nurse-led model, with additional training and support for how to interpret AI reports felt to be needed to aid delivery. The UK concordance study abstract by Polaris (2025) reported that clinician user feedback on ArtiQ.Spiro was positive, highlighting its potential to enhance workflow efficiency. The EAG rated this outcome as being GREEN in their evidence gap analysis for ArtiQ.Spiro (see Table 38 in the EAR).

LungHealth

Angus et al. (2012) reported on feedback (measured via a Likert scale) from 7 nurses without previous specialty respiratory training after using LungHealth software following a 2-day mentoring period, see Table 14 in the EAR. The EAG note that during this mentoring period that the staff had additional support from a trained respiratory nurse. Therefore, the generalisability of these results may not be reflective of how the technology would be used in NHS. The EAG rated this outcome as being AMBER in their evidence gap analysis for LungHealth (see Table 38 in the EAR).

MIR Spiro

Lusuardi et al. (2006) reported that 57.1% of 104 GPs found MIR Spirobank Office to be very useful, 15.0% reported it to be moderately useful and 0.3% reported it to be useless. The EAG rated this outcome as being AMBER in their evidence gap analysis for MIR Spiro (see Table 38 in the EAR).

NuvoAir

Kocks et al. (2023) reported that of 24 practice nurses and 4 GPs, 82% agreed that home spirometry was possible, executable (78%) and implementable (68%). Only 50% agreed that NuvoAir was easy to use although it is unclear whether this relates to ease of use experienced by patients or aspects of the technology being used by the clinician, such as viewing reports or engaging with the NuvoAir physiologists. See table 23 in the EAR. The EAG rated this outcome as being AMBER in their evidence gap analysis for NuvoAir (see Table 38 in the EAR).

5.14 Health-related quality of life

No studies were identified that reported this outcome for any of the included technologies. For all intervention technologies, the EAG rated this outcome as being RED (see Table 38 in the EAR).

5.15 Patient acceptability, ease of use, experience and satisfaction

ArtiQ.Spiro

Doe et al. (2025b) obtained feedback from 9 patients undergoing spirometry in primary care to explore the use of AI decision support software for spirometry interpretation. Themes included that AI is likely a positive addition to healthcare, however the human element of diagnosis and decision making should not be lost from clinical care, and clinicians should retain oversight of the report and diagnostic outcomes. Participants noted that there may be benefits (not stated) to speeding up the process for their spirometry results. The EAG rated this outcome as being AMBER in their evidence gap analysis for ArtiQ.Spiro (see Table 38 in the EAR).

GoSpiro

Rydberg et al. 2023 reported patient feedback on the use of GoSpiro spirometer for home COPD monitoring, where 45.5% of 12 respondents reported that the spirometer was mostly or extremely easy to use. The EAG

rated this outcome as being AMBER in their evidence gap analysis for GoSpiro (see Table 38 in the EAR).

MIR Spiro

Two studies (Khatoon et al., 2025; Castro et al., 2024) reported patient views on home spirometry testing. Both studies collected views on the use of the spirometers themselves, in diagnosed populations of patients. See table 18 in the EAR. The EAG rated this outcome as being AMBER in their evidence gap analysis for MIR Spiro (see Table 38 in the EAR).

NuvoAir

Results from 4 studies are reported in table 24 of the EAR. Key results include:

- Coughlin 2021 reported that of 18 parents and carers of paediatric patients, 82.4% found NuvoAir to be easy to set up, and 81.3% found it easy to perform spirometry using NuvoAir.
- Gray (2026) reported that [redacted] would recommend NuvoAir home monitoring service.
- Kocks (2023) reported that of 101 adults with asthma or COPD, 10% found NuvoAir app instructions unclear, 17% experienced problems, 81% felt safe performing NuvoAir home spirometry, and 24% needed help from a professional.

The evidence was largely in diagnosed populations, as such the EAG rated this outcome as being AMBER in their evidence gap analysis for MIR Spiro (see Table 38 in the EAR).

5.16 Ongoing studies

A total of 10 ongoing studies were identified across 4 manufacturers (2 for ArtiQ.Spiro, 1 for LungHealth, 2 for MIR Spiro and 5 for NuvoAir) with varying relevance to the scope of this assessment. See table 37 in the EAR.

6. Health economic evidence

The external assessment group (EAG) did a review to identify suitable health economic models, see section 6.1 in the EAR. From the economic search (including reference trawling of identified reviews), 11 papers were considered partly relevant to inform development of a conceptual economic model which could be used to determine key drivers and areas of uncertainty. This included 4 papers in asthma, 5 in COPD and 2 in restrictive lung disease populations (summarised in Appendix B1). Three companies also provided specific economic evidence related to the technologies listed in the scope, see table 25 in the EAR.

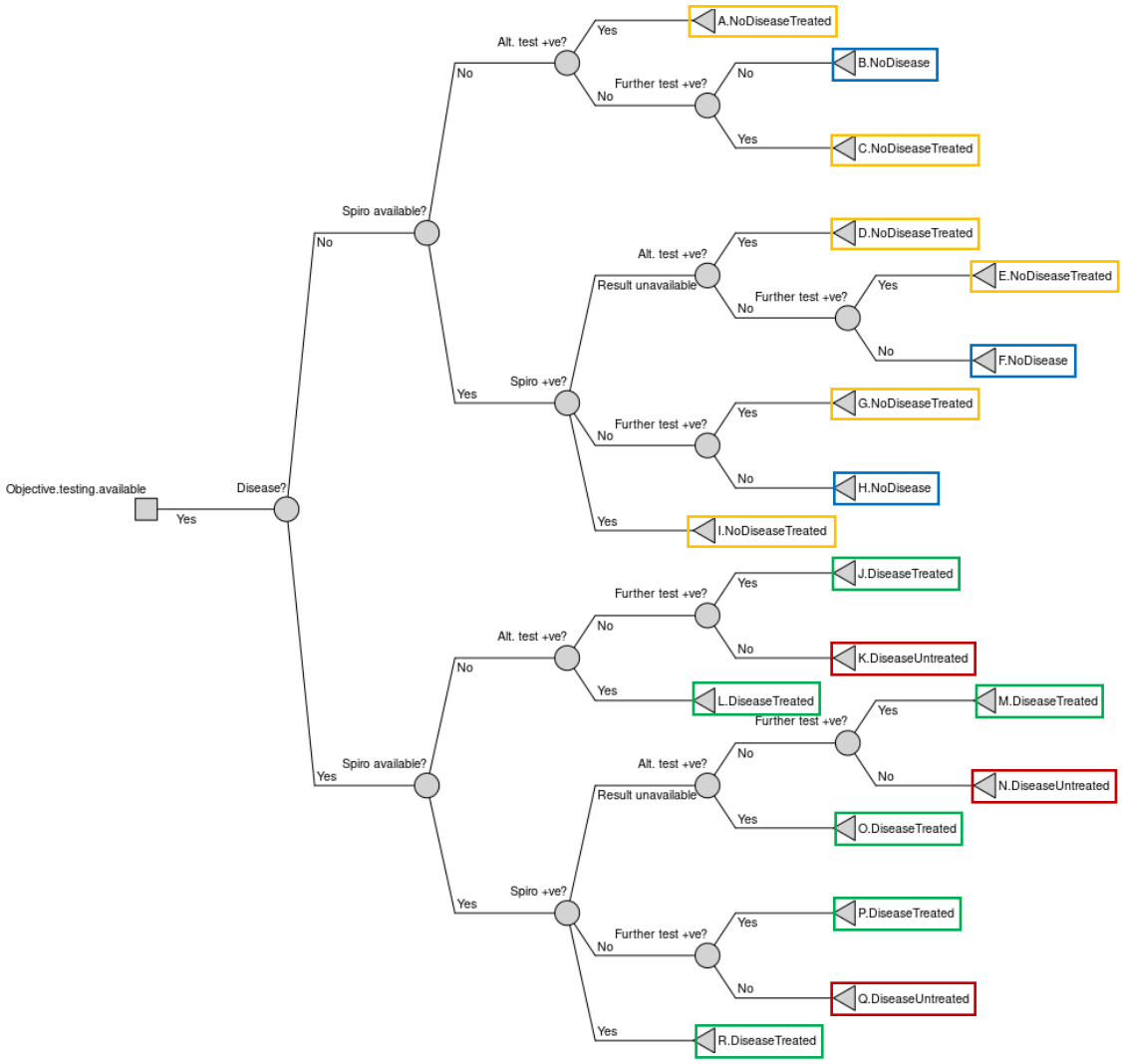
The EAG also reviewed NICE clinical guidelines for relevant economic models. This included the economic analysis used to support the update of BTS/NICE/SIGN collaborative guideline NG245 on diagnosis, monitoring and chronic asthma management (NG245, 2024), and NG115 on the diagnosis and management of chronic obstructive pulmonary disease in over 16s (NG115, 2019).

6.1 Conceptual health economic model

Model structure

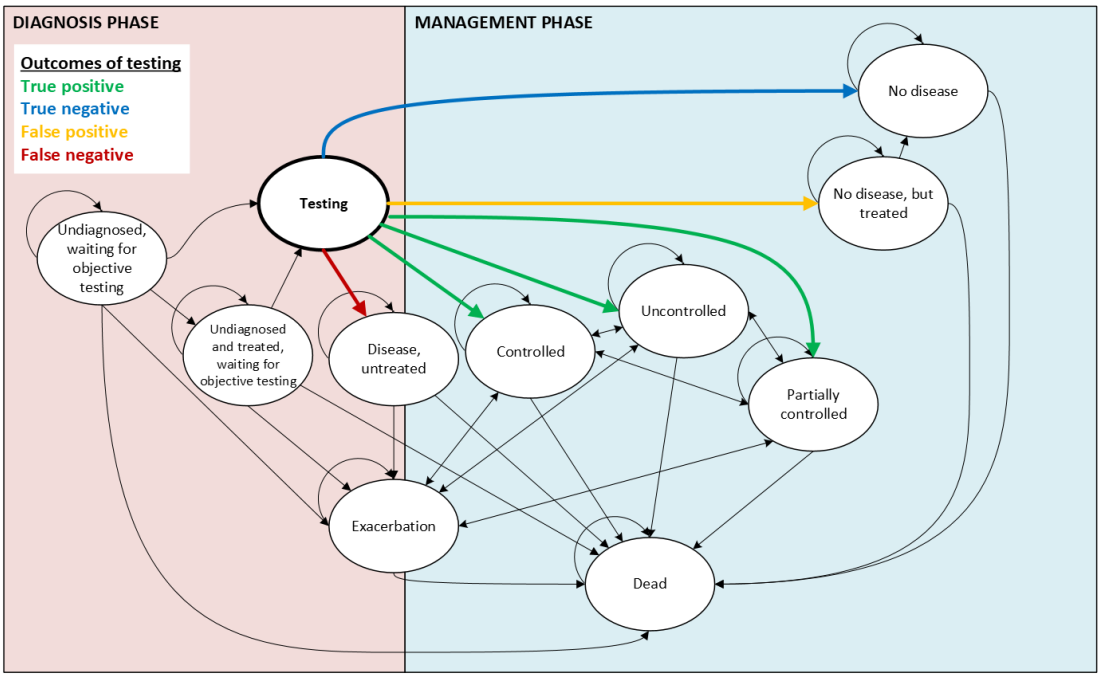
The EAG developed a conceptual economic model where the general structure would apply to all asthma, COPD and restrictive lung disease populations in scope. The structure incorporated a decision tree (Figure 1) to model the diagnostic phase, which is embedded within a **Testing** state of a Markov model (Figure 2) 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 EAR

Figure 1: Conceptual model decision tree



Key: Green=True positive, Blue=True negative, Yellow=False positive, Red=False negative

Figure 2: Conceptual Markov model



The model was based on methods and assumptions from published economic resources (NG245, NG115) to demonstrate key drivers and areas of uncertainty. Assumptions include:

- Patients may die or suffer an exacerbation while in the **Undiagnosed, Disease (untreated)** or **Undiagnosed but treated** states. It is assumed that once in the **Exacerbation** state, diagnosis is achieved by other means and patients move to the management phase and cannot return to the **Undiagnosed** states, or **Disease (untreated)** state.
- Exacerbation and mortality are the only adverse events included in the modelling. Additional adverse event states could be added to the economic model in future should more data become available.
- Testing before objective testing is available is not modelled, assuming costs will be incurred equally in both intervention and comparator arms and will diagnose the same proportion of the starting population.
- Each patient can only visit the **Testing** state and pass through the testing decision tree once.

- Different disease severity states (for example, GOLD categories for COPD) within the economic modelling are not considered, with an average event rate used across severity states.
- Different levels of symptom control have been modelled, but the natural history and disease progression of the disease were not.
- It is assumed that patients with a false positive result will be treated as if they do have the condition, and will be placed on inappropriate treatment that is unlikely to resolve their symptoms, and may cause harm.
- The use of biologics in a population with severe difficult-to-treat asthma is considered indirectly (not explicitly) within sensitivity analysis by increasing the management costs and adjusting utilities within states that include treatment.
- Costs of different severities of exacerbation are modelled as a weighted average (see Table 28 in the EAR) and applied to transitions into the **Exacerbation** state. The base case assumes that 95% of those within the **Exacerbation** state leave that state within 1 month before transitioning into other management (fully controlled, partially controlled, uncontrolled) states.
- Utilities applied in the **Exacerbation** state are those used in NG245, adjusted using a utility multiplier.
- The input utility table only includes data for those aged 16 and over. Therefore, for children under 16, a baseline utility for a 16 year old has been used.
- In the conceptual model cohorts of adults and children are modelled separately to enable illustration of uncertainties. For the child population, which uses a minimum starting age of 6 years old, a maximum time horizon of 10 years is allowed, at which point they would need to be modelled as an adult.
- For generalisability of the model between conditions, extra tests alongside spirometry to diagnose COPD have not been modelled.

- Rates of exacerbation and death from health states containing an undiagnosed population are calculated based on the prevalence of the disease.

6.2 Model inputs

The EAG note that the model lacked full parameterisation and as such the results should not be interpreted as evidence or lack of evidence of cost-effectiveness.

Clinical parameters

The clinical parameters of the conceptual model for asthma (separated by adults and children) and COPD are described in Table 26 in the EAR.

- The starting age in the model for adults with asthma was 30, children with asthma was 6, and adults with COPD was 50.
- Transition rates to and from the different Markov states were derived from a number of sources including NG245, other publications (e.g. Howard (2023), Van de Hei et al. (2023) and Lambe et al. (2019)), expert opinion and EAG assumption.
- Exacerbation rates in the **Controlled** state were taken from NG245. Exacerbation rates in **partially controlled** and **uncontrolled** states were assumed to be 2.5% and 5% higher respectively compared to those in the **Controlled** state.
- Exacerbation rates in the **undiagnosed, treated**, **undiagnosed, waiting testing** and **testing** states were calculated fields in the model
- Probability of spirometry being available was assumed to be 0.33 in the base case for asthma, and 1.00 for COPD (in line with NG115, spirometry must be used to diagnose COPD).
- In the base case, diagnostic accuracy (sensitivity and specificity) of spirometry in the comparator arm was taken from NG245, with a 10% increased sensitivity assumed in the intervention arm (explored further in sensitivity analysis).

- Mortality of the general population is age and gender specific (Office for National Statistics, 2025). Hazard ratios were assumed and applied to standardised mortality rates for other Markov states.

Many of these parameters were varied in sensitivity analysis (see Table 32 in the EAR).

Resource use and cost parameters

Intervention costs for LungHealth were applied in the base case (£63.45 per person), with sensitivity analysis including a range of costs to reflect what may be observed for other intervention technologies (ArtiQ.Spiro, GoSpiro and NuvoAir). Technology costs were absent for 2 of 6 technologies in scope, EasyOne Connect and MIR Spiro. These technologies were not included in economic modelling. A cost of £37.24 was applied to the standard care arm of the model. See Table 27 in the EAR.

Technology costs were comprised of:

- Generic cost of a spirometer. This cost was taken from NG245 and applied where additional hardware was required.
- Spirometer calibration and consumables
- Staff time: assumed 30 minutes of a practice nurse for measurement, and 10 minutes for interpretation in standard care. Staff costs associated with practice nurse time for initial measurement and interpretation were applied using hourly rates reported by Jones et al. (2024), taken to be a band 5 nurse with qualifications, costed at £53 per hour. Five minutes of measurement and 5 minutes of interpretation time were assumed to be saved when using ArtiQ.Spiro, MIR Spiro, EasyOne Connect and GoSpiro (clinic) technologies, giving model input of £22.08 and £4.42 respectively. Measurement and interpretation were removed completely for NuvoAir which represents a service (in which the cost is assumed to be within the cost per patient provided by the company).
- Integration costs (intervention arm only), which the EAG applied to all technologies at a cost of approximately £2.38 per patient.

- Mobile phone and internet access (for home-based technologies only), at a cost of £12.10 per patient.

Additional costs associated with the diagnostic pathway, management pathway and treatment of adverse events (exacerbations) are described in Tables 28, Table 29 and Table 30 of the EAR.

Utility parameters

Baseline utilities applied in the model were age and gender specific, taken from NICE's Decision Support Unit (Hernández Alava, et al., 2022). The minimum age was 16 years; hence all children in the model have utility for a 16-year-old applied.

Utility multipliers for different Markov states (undiagnosed, controlled, partially controlled, uncontrolled or exacerbation) in people with asthma were taken from NG245, and were based on assumptions or NG115 for COPD. Quality-adjusted life years (QALYs) lost for a false positive diagnosis were set to 0 in the base case for asthma (adults and children) and COPD. See table 31 in the EAR.

6.3 Model results

Base case

A summary of the base case model results (using LungHealth costs) are shown below in Table 2, and in Tables 33, 34 and 35 of the EAR. Results are presented for 2 base case scenarios for each disease group, based on the value propositions of the included technologies:

- Increased diagnostic accuracy: 10% increase in sensitivity assumed in the intervention arm
- Faster access to objective testing: for the intervention arm, 70% tested within 6 months was assumed (compared to 63.2% for the comparator).

Table 2: Base case model results

	Description	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£ per QALY)
Value proposition 1 (higher diagnostic accuracy)						
Asthma (adults)	Comparator + 37% sensitivity	593.3	6.829	N/A	N/A	N/A
	Intervention + 47% sensitivity	598.7	6.829	5.406	0.0004393	12,307
Asthma (children)	Comparator + 68% sensitivity	661.3	7.375	N/A	N/A	N/A
	Intervention + 78% sensitivity	668.2	7.377	6.866	0.001188	5,781
COPD	Comparator + 37% sensitivity	787.4	6.076	N/A	N/A	N/A
	Intervention + 47% sensitivity	802.3	6.079	14.92	0.002498	5,974
Value proposition 2 (increased rate of access to objective testing)						
Asthma (adults)	Comparator + 63.2% tested in 6 months	593.3	6.829	N/A	N/A	N/A
	Intervention + 70% tested in 6 months	604.8	6.831	11.5	0.002771	4,152
Asthma (children)	Comparator + 63.2% tested in 6 months	661.3	7.375	N/A	N/A	N/A
	Intervention + 70% tested in 6 months	673.6	7.377	12.29	0.002101	5,849
COPD	Comparator + 63.2% tested in 6 months	787.4	6.076	N/A	N/A	N/A
	Intervention + 70% tested in 6 months	813.8	6.086	26.38	0.009178	2,874

Abbreviations: quality-adjusted life years (QALYs); incremental cost-effectiveness ratio (ICER), not applicable (N/A)

Asthma (adults)

Assuming that the intervention arm had a 10% increase in diagnostic sensitivity (when compared with standard care) gave an incremental cost of £5.78 per patient and 0.0004393 incremental QALYs gain, resulting in an ICER of £12,307 per QALY. Assuming faster access to objective testing with

the intervention gave an incremental cost of £11.50 per patient, and incremental QALYs were 0.002771, resulting in an ICER of £4,152 per QALY.

Asthma (children)

For a 10% increased sensitivity in the intervention arm, the incremental cost was £7.38 and incremental QALYs were 0.001188, resulting in an ICER of £5,781 per QALY. Assuming faster access to testing in the intervention arm, the incremental cost was £12.29, and incremental QALYs were 0.002101, resulting in an ICER of £5,849 per QALY. See section 6.3.2 of the EAR.

COPD

Larger QALY gains were observed in a COPD population than in the asthma populations, because larger differences were assumed between utility multipliers applied to levels of symptom control for COPD than for asthma. Increasing the diagnostic sensitivity of the intervention by 10% over a 10-year time horizon, the intervention was associated with an incremental cost of £14.92 and difference of 0.002498 QALYs, resulting in an ICER of £5,974 per QALY. Assuming a higher proportion receive objective testing, the incremental cost was £26.38 and incremental QALY gain was 0.009178, giving an ICER of £2,874 per QALY. See section 6.3.3 of the EAR.

Scenario and sensitivity analyses

To determine the key drivers from the economic modelling and to inform future data collection efforts, the EAG focused on univariate deterministic sensitivity analysis (see Table 32 of the EAR). Results show that the model is most sensitive to changes in diagnostic accuracy (sensitivity and specificity) and technology costs.

Asthma (adults)

The adult asthma model was sensitive to univariate changes in the diagnostic accuracy of the intervention, and technology costs per patient. ICERs were above £20,000 per QALY when:

- Sensitivity was less than 9% higher in the intervention arm than the comparator arm (assuming a fixed specificity) or specificity was below 88%

(assuming a fixed sensitivity). Using results from SPIRO-AID (sensitivity of [redacted]% and specificity of [redacted]% for ArtiQ.Spiro) the intervention arm would be considered dominant. A lack of diagnostic accuracy evidence for other technologies in-scope meant the EAG was unable to comment on the plausibility of these sensitivity and specificity thresholds.

- Technology cost was £74 or more per patient (assuming sensitivity is 10% higher for the intervention). This applies to NuvoAir, and the EAR outlines the criteria necessary for this technology to achieve an ICER below £20,000 per QALY. When the costs of ArtiQ.Spiro and GoSpiro were applied, cost savings were £4.01 and £3.56 per patient respectively, making these interventions dominant. The EAG tested a scenario in which a GP is assumed to interpret spirometry (instead of a band 5 practice nurse as in the base case). ArtiQ.Spiro and GoSpiro remained dominant, NuvoAir still had an ICER above £20,000/QALY but the ICER for LungHealth also became above £20,000/QALY. Therefore, the economic model is sensitive to per patient costs including the banding and time of staff used to measure and interpret spirometry findings.

Other parameters to which the asthma (adult) model was sensitive are initial prevalence of disease, time horizon and costs of further testing (if spirometry or the alternative, peak flow, are negative). See section 6.3.1.3 of the EAR.

Asthma (children)

The asthma (children) model was sensitive to univariate changes in the diagnostic accuracy of the intervention, and technology costs per patient. ICERS were above £20,000 per QALY when:

- Sensitivity was less than 5% higher in the intervention arm than the comparator arm (assuming a fixed specificity). Increasing specificity above 88% resulted in the intervention being dominant.
- Technology cost was £117 or more per patient (assuming sensitivity is 10% higher for the intervention). This applies to NuvoAir, and the EAR outlines the criteria necessary for this technology to achieve an ICER below £20,000 per QALY. When the costs of ArtiQ.Spiro and GoSpiro were

applied, the incremental cost savings of £2.57 and £2.12 respectively per patient made these interventions dominant. In the scenario assuming a GP interprets spirometry ArtiQ.Spiro and GoSpiro remained dominant, NuvoAir still had an ICER above £20,000/QALY, but the increase in incremental costs per patient did not result in an ICER greater than £20,000/QALY for LungHealth (unlike the adult asthma population).

Other parameters to which the asthma (children) model was sensitive are initial prevalence of disease and time horizon. See section 6.3.2.3 of the EAR.

COPD

The COPD model was sensitive to univariate changes in the diagnostic accuracy of the intervention, and technology costs per patient:

- Sensitivity of the intervention greater than 64% meant the intervention was considered dominant. Using results from the SPIRO-AID study, ArtiQ.Spiro had an incremental cost saving of £[redacted], incremental QALY gain of [redacted] resulting in the intervention being dominant.
- Technology cost was £100 or more per patient (assuming sensitivity is 10% higher for the intervention). When modelling the costs of ArtiQ.Spiro and GoSpiro, the intervention was considered dominant because of cost savings of £12.65 and £11.34 per patient respectively. By assuming interpretation was conducted by a GP; ArtiQ.Spiro and GoSpiro remained dominant, NuvoAir still had an ICER greater than £20,000/QALY and LungHealth had an ICER of £19,467/QALY.

Other parameters to which the COPD model was sensitive are initial prevalence of disease and time horizon. See section 6.3.3.2 of the EAR.

7. Evidence gaps

The EAG's evidence gap analysis is presented is discussed in section 8.2 of the EAR.

Population gaps

- Limited evidence was available in an undiagnosed population for all technologies and suspected diseases (asthma, COPD and ILD), except for ArtiQ.Spiro
- Evidence is limited in people with suspected restrictive lung conditions and only available for ArtiQ.Spiro

Intervention gaps

- Evidence in-scope was absent for EasyOne Connect
- Limited evidence limited for GoSpiro and MIR Spiro
- General lack of transparent reporting of the software name, version and associated hardware used

Comparator gaps

- Other than for ArtiQ.Spiro, there is a lack of comparative evidence (compared with a reference standard) to show the accuracy of the technologies for spirometry quality assessment and interpretation, and their impact on resource use, including waiting times, staffing and resources.

Outcome gaps

- Lack of diagnostic accuracy (sensitivity and specificity) data for all but ArtiQ.Spiro.
- Lack of longitudinal outcomes, including mortality, morbidity, time-to-diagnosis, staff time and resource use, number of secondary care referrals for diagnosis and hospital admissions because of missed diagnosis or treatment.

8. Equality considerations

The final scope and the scoping equality impact assessment describe equality considerations for this assessment. Considerations to ensure the technologies do not add to health inequalities include:

- The patient population used in the training and validation set for artificial intelligence (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 AI

In addition, the EAG noted considerations of digital inclusion for patient-facing technologies. This includes language options for non-native speakers.

9. Key points, limitations and considerations

9.1 Clinical effectiveness

Key points

- The most comprehensive evidence was for ArtiQ.Spiro, in terms of quality, generalisability to a UK NHS setting and for populations and outcomes in scope. Further evidence collection may help to ensure generalisability of the these results in a larger population in a real-world NHS context.

- Evidence of accuracy of quality assessment and interpretation (when compared with standard care) in an undiagnosed population is limited for 5 technologies (EasyOne Connect, GoSpiro, LungHealth, MIR Spiro, NuvoAir).

- Diagnostic accuracy evidence (in an undiagnosed population) is lacking across technologies other than ArtiQ.Spiro. Because of differences in functionality and implementation requirements between technologies, and lack of data comparing the technologies against each other, the EAG cannot assume clinical equivalence of the other technologies to ArtiQ.Spiro

9.2 Health economic evidence

Key points:

- The EAG note that results from this modelling work should not be interpreted as evidence or lack of evidence of cost-effectiveness. Instead, this modelling work has highlighted key evidence gaps and key drivers (see Table 36 in the EAR) of differences in costs and utilities of technologies used to support spirometry interpretation when compared with standard care.

- EasyOne Connect and MIR Spiro were not included in economic modelling. Due to the lack of data available for the EAG within this assessment, no economic modelling was conducted for restrictive lung disease.

- Conceptual economic modelling has shown that the model is most sensitive to sensitivity and specificity and technology costs (including staff band and time used to measure and interpret spirometry in the comparator and with each of the technologies). Small differences in long-term outcomes may not significantly impact the overall cost-effectiveness of the technologies. Therefore, the value of requesting longer-term outcomes in future data collection should be carefully considered

- Conceptual economic modelling demonstrated that it was plausible that each of the technologies included in modelling could be considered cost effective (using a willingness to pay threshold of £20,000 per QALY) in some scenarios. Univariate economic modelling (and in-confidence data from the SPIRO-AID randomised controlled trial) suggests that it is plausible that ArtiQ.Spiro could be cost-effective when used to support diagnosis of lung conditions in primary care. Evidence is lacking to draw similar conclusions on the other interventions.

Considerations for committee:

- Are the economic model structure and assumptions appropriate to assess the potential cost-effectiveness of the technologies?

- Are the clinical and cost parameters suitable to answer the decision question (see final scope) for this assessment?
- What can the model results tell us about the comparative cost-effectiveness of the interventions?
- Are the model results generalisable to people with restrictive lung disease?
- Which data gaps are most important to address?

Appendix A Abbreviations

CI	Confidence interval
COPD	Chronic obstructive pulmonary disorder
EAG	External assessment group
EAR	External assessment report
FEV1	Forced expiratory volume in 1 second (the amount of air exhaled in the first second of a forced breath).
FVC	Forced vital capacity (the amount of air a person can forcefully exhale after taking a deep breath)
ICER	Incremental cost-effectiveness ratio
ILD	Interstitial lung disease
NMB	Net monetary benefit [delete if not needed]
QALY	Quality-adjusted life year [delete if not needed]
RCT	Randomised controlled trial [delete if not needed]

GID-HTE10065 Algorithms applied to spirometry to support diagnosis of lung conditions in primary care and community diagnostic centres

External assessment report

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Number of attached appendices: 4

Purpose of the early value assessment report

The purpose of this external assessment report (EAR) by an external assessment group (EAG) for early value assessment is to review the evidence currently available for technologies within the decision problem and advise what further evidence should be collected to help inform future decisions on whether the technologies should be widely adopted in the NHS. NICE has commissioned this work and provided the template for the report. The report forms part of the papers considered by the Committee when it is making decisions about the early value assessment.

Declared interests of the authors

Description of any declared interests with related companies, and the matter under consideration. See NICE's Policy on managing interests for board members and employees.

None.

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Responsibility for report

The views expressed in this report are those of the authors and not those of NICE. Any errors are the responsibility of the authors.

Abbreviations

Term	Definition
A&E	Accident and emergency
AI	Artificial intelligence
ARTP	Association for Respiratory Technology and Physiology
ATS	American Thoracic Society
AUROC	Area under the receiver operating characteristic curve
BDR	Bronchodilator reversibility
BMI	Body mass index
BTS	British Thoracic Society
CCG	Clinical Commissioning Group
CEA	Cost effectiveness analysis
CI	Confidence interval
COPD	Chronic Obstructive Pulmonary Disease
DD	Differential diagnosis
DHSC	Department of Health and Social Care
DPI	Dry powder inhaler
EAG	External assessment group
EAR	External assessment report
ERS	European Respiratory Society
EVA	Early value assessment
FeNO	Fractional exhaled nitric oxide
FEV1	Forced expiratory volume in 1 second
FVC	Force vital capacity
FVL	Flow volume loop
GOLD	Global Initiative for Chronic Obstructive Lung Disease
GP	General practitioner
HES	Hospital Episode Statistics
HR	Hazard ratio
ICER	Incremental cost-effectiveness ratio
ICS	Inhaled corticosteroids
IgE	Immunoglobulin E
ILD	Interstitial lung disease
IPF	Idiopathic pulmonary fibrosis
ISO	International Organization for Standardization
IQR	Interquartile range
LABA	Long-acting beta-2 agonist
LAMA	Long-acting muscarinic antagonist
MDI	Metered dose inhaler
MHRA	Medicines & Healthcare products Regulatory Agency
MIR	Medical International Research
N/A	Not applicable
NMB	Net monetary benefit
NPV	Negative predictive value
NR	Not Reported
NRAP	National Respiratory Audit Programme

Term	Definition
NSIP	Nonspecific interstitial pneumonitis
PD	Preferred diagnosis (top category with highest probability score with AI)
PEF	Peak expiratory flow
PEFv	Peak expiratory flow variability
PFTs	Pulmonary function tests
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSA	Probabilistic sensitivity analysis
QALY	Quality-adjusted life year
RCT	Randomised controlled trial
RR	Relative risk
SABA	Short-acting beta-2 agonist
SaMD	Software as a Medical Device
SD	Standard deviation
SIGN	Scottish Intercollegiate Guidelines Network
VAS	Visual analogue scale

Executive summary

Background and aims: Lung disease is a leading cause of death in the UK, with conditions such as asthma and chronic obstructive pulmonary disease (COPD) accounting for 3.4% total NHS annual expenditure (Foster 2023). The NHS 10-Year Plan has recognised respiratory medicine as a priority and is focused on using innovative and digital technologies to improve quality of healthcare. Earlier or more accurate diagnosis of lung conditions may reduce NHS expenditure, through optimising treatment and reducing exacerbations and hospitalisations (Foster 2023). The use of digital technologies that use artificial intelligence (AI)-derived or rules-based algorithms supporting spirometry in primary care has been identified as a key area where improvements in diagnostic accuracy and efficiency gains may be realised (Doe et al. 2023; Warren 2023). These technologies may provide additional assurances of test quality or interpretation, which could improve the accuracy of diagnosis or reduce the time taken to interpret the test results.

The purpose of this early value assessment (EVA) was to identify and summarise the available evidence for six technologies (ArtiQ.Spiro, EasyOne Connect, GoSpiro, LungHealth, MIR Spiro, NuvoAir), which use algorithms to support spirometry testing in primary care or community diagnostic centres, compared with standard care. The assessment focused on the use of spirometry to support diagnosis of asthma, COPD or restrictive lung disease. A conceptual economic model was developed to identify key uncertainties for implementation in the NHS. Areas for evidence generation to address uncertainties and inform the key drivers of the model were identified to direct further research and data collection to inform a future full evaluation.

Technologies: All technologies included in this EVA use algorithms based on international guidelines to support spirometry quality and diagnostic evaluation. The assessment of spirometry quality may therefore be similar across the technologies in scope, driven by the adherence to the same or comparable guidelines. Four technologies also reported the application of AI-derived algorithms; with limited reporting for all technologies except for

ArtiQ.Spiro of how algorithms were trained and validated. Therefore, the generalisability of evidence between technologies is unknown. Each technology may also be implemented into the diagnostic pathway differently: ArtiQ.Spiro is a software adjunct to existing spirometers; EasyOne Connect and MIR Spiro are software compatible with their respective manufactured spirometers; GoSpiro encompasses a software and hardware spirometry solution; LungHealth is a computer-guided consultation adjunct to existing spirometry services; NuvoAir is an independent home-based spirometry diagnostic programme including repeated measurements. Cost, resource, and some clinical outcomes (such as time to perform and interpret spirometry or time-to-diagnosis) may therefore not be generalisable between technologies.

Clinical evidence: The EAG conducted literature searches and reviewed evidence submitted by the companies and Experts. Only 8 studies reporting use of 3 technologies were conducted in an exclusively undiagnosed population. Because of this, the EAG broadened elements of the scope to include people who had an existing diagnosis of asthma, COPD or ILD where outcomes relating to diagnostic accuracy and user experience of the technology were reported. This approach also enabled the EAG to consider the use of the included technologies to inform a change in diagnosis, which may offer clinical benefits to patients and resource benefits to the NHS. The EAG note that algorithm function may not fundamentally differ between people with or without a diagnosed lung condition, however the use of the technologies in people who are familiar with the spirometry test may improve the overall quality and validity of the test.

The EAG included a total of 30 relevant sources of evidence for the technologies; ArtiQ.Spiro (N=11), GoSpiro (N=1), LungHealth (N=9), MIR Spiro (N=3), and NuvoAir (N=6). No evidence in scope of this EVA was identified for EasyOne Connect or its respective compatible spirometers. Evidence, largely UK real-world studies, comprised 14 abstracts, 7 full publications, 4 posters, 2 pre-print publications, 1 editorial, with 2 further sources provided as academic-in-confidence by 1 company.

The evidence base was most comprehensive for ArtiQ.Spiro. This included a UK randomised-controlled trial (RCT) that aligned with the scope of this assessment; comparing the performance of primary care clinicians conducting spirometry in UK NHS primary care with and without software support against a secondary care expert panel reference standard (Doe et al. 2025a). Authors reported an improvement in test accuracy grading and interpretation with the use of ArtiQ.Spiro. The EAG note that the sample sizes were small (greatest disease prevalence represented in the dataset was COPD with 20 patients and asthma with 6 patients). However, trial data was shared with the EAG such that sensitivity and specificity could be calculated (Appendix D4). Sensitivity and specificity data for ArtiQ.Spiro was publicly available from a UK diagnostic accuracy validation study (Sunjaya et al. 2025), which reported technology performance against a secondary care expert panel reference standard including 1,113 patients.

RCT evidence was also available for a MIR Spiro compatible spirometer, which compared diagnostic accuracy of GPs with or without access to the spirometer in an Italian primary care setting against a secondary care expert panel reference standard (Lusuardi et al. 2006). Authors reported that the level of agreement between GPs and specialists was not found to be statistically significantly different regardless of whether spirometry was performed. Due to the date of publication, the EAG note that the study is unlikely to reflect the current version of the technology, and sensitivity and specificity for each arm was not reported.

Comparative evidence was not available for LungHealth or GoSpiro, and not available for diagnostic or quality assessment accuracy outcomes for NuvoAir, therefore sensitivity and specificity of these technologies is currently unavailable. Evidence for LungHealth and NuvoAir broadly focused on its use in people with an existing diagnosis of asthma or COPD and included non-comparative evidence that reported the number of people who had a change in diagnosis following use of the technologies. Comparative evidence for the impact of the technologies on time to perform and interpret spirometry was

only available for ArtiQ.Spiro, reporting a reduction in appointment and interpretation time when using the technology.

Economic evidence: The EAG reviewed 5 economic evaluations specific to three technologies (ArtiQ.Spiro, LungHealth, NuvoAir) provided by the companies, 11 additional economic evaluations that were not directly relevant to the decision problem, and 2 economic reports which were developed for NICE guidance in asthma (NG245) and COPD (NG115). This evidence contributed to the development of a conceptual economic model, which was built by the EAG to facilitate modelling of multiple value propositions (increased diagnostic accuracy and reduced waiting times for spirometry) associated with the technologies in scope. Results from this modelling work should not be interpreted as evidence or lack of evidence of cost-effectiveness. Instead, this modelling work aimed to determine key evidence gaps and key drivers of differences in costs and utilities compared with standard care, which should be addressed before a definitive evaluation is conducted.

The EAG conducted extensive univariate sensitivity analysis to determine the key drivers and uncertainties associated with technologies being used to support interpretation of spirometry in a diagnostic pathway when compared with standard of care in the NHS. The EAG identified that the model was sensitive to univariate changes in diagnostic accuracy and per-patient cost of the technology (for example when applying the cost of NuvoAir), which had the potential to increase the ICER above the willingness to pay threshold of £20,000/QALY. However, conceptual economic modelling conducted by the EAG demonstrated that it was plausible that each technology could be considered cost effective using a willingness to pay threshold of £20,000/QALY in some scenarios. This economic model framework could be used in the future when more data becomes available.

Key points for decision makers:

- The scope of this EVA is broad, capturing a) multiple populations (adults and children with suspected lung conditions undergoing spirometry to support initial diagnosis including asthma, COPD or restrictive lung conditions such as ILD), b) six technologies all with differences in how they might be implemented within the NHS, and c) multiple settings (primary care, community diagnostic centres or home-based assessment).

- Technologies in scope of this EVA share a value proposition to support quality assurance and interpretation of spirometry informing a diagnosis of lung conditions, such as asthma or COPD in primary care using algorithms applied to spirometry. However, each may be implemented into the NHS differently and as such, may result in differences in key economic model drivers such as waiting times (for testing and diagnosis) and resource use, potentially limiting the generalisability of evidence across technologies.

- Limited evidence was available in an undiagnosed population for all technologies except for ArtiQ.Spiro. However, the EAG note that the performance of rules-based algorithms using international clinical guidelines may not differ significantly between diagnosed and undiagnosed populations. Four technologies also use AI-derived algorithms to support spirometry assessment. As there is a lack of evidence, particularly comparative evidence, it is not possible to fully understand the generalisability of outcomes between populations or technologies.

- Evidence for ArtiQ.Spiro suggests that the use of technologies using algorithms to support diagnosis in primary care may release resources driven by a reduction in test interpretation time and changes in staff delivering spirometry testing. Because of differences in implementation between technologies and a lack of comparative evidence, it is unclear whether this may be generalisable across all technologies.

- Limited or a lack of comparative evidence for five technologies (EasyOne Connect, GoSpiro, LungHealth, MIR Spiro, NuvoAir) results in uncertainties in diagnostic accuracy in an undiagnosed population. Diagnostic accuracy is a key driver within the economic modelling.

- The costs of two technologies (MIR Spiro, EasyOne Connect) were unknown. The costs associated with NuvoAir resulted in an ICER greater than £20,000/QALY and large negative NMB; therefore, additional information is required to understand the cost implications of implementing this technology (for example the number of patients using this technology for home-based spirometry to support diagnosis, and NHS costs avoided).

- Evidence is limited in people with suspected restrictive lung conditions and only available for ArtiQ.Spiro. The EAG acknowledges that the diagnostic pathway for ILD may involve imaging and a multidisciplinary team to inform a diagnosis rather than being based on spirometry within a primary care setting. However, patients may present in primary care and therefore earlier detection may result in earlier treatment in this population. Additionally, changes in lung function identified through spirometry may be used to support the appropriate timing of diagnostic imaging. Further data collection in this patient population would support definitive evaluation.

- Evidence generation should focus on the collection of comparative evidence relating to diagnostic accuracy in an undiagnosed population across separate cohorts with suspected COPD, asthma or restrictive lung disease. Additionally, better understanding the use case and costs associated with implementing home-spirometry testing with technologies, such as NuvoAir would support future economic evaluation.

1. Decision problem

The decision problem is described in the Final Scope and EAG comments are included in the EAG Protocol.

To enable a more comprehensive appraisal of the technologies in scope, in line with Section 2.1 of the EAG Protocol, the EAG:

- broadened the inclusion criteria to identify evidence for the included technologies, notably the EAG considered evidence in people with an existing diagnosis of asthma, chronic obstructive pulmonary disease (COPD) or interstitial lung disease (ILD), especially for outcomes associated with diagnostic accuracy.
- Excluded studies where the only outcome in scope reported was quality assurance of spirometry test performance or adherence to spirometry testing in populations with an already diagnosed lung condition (including asthma, COPD, or ILD), such as when using spirometry for monitoring purposes.
- Considered patient and clinician usability evidence in people with a diagnosis as these outcomes were unlikely to differ by population (undiagnosed or with a lung condition diagnosis), which was an approach supported by two Experts (Appendix D1). However, the EAG did not consider patient and user experience relating to spirometry used for monitoring, such as value in providing support for condition management as this is out of scope.
- Applied exclusion criteria of animal or lab-based studies, non-English publications, those specifically comparing parameters between spirometers and studies that reported algorithm or AI development or training.

The EAG note that the included technologies apply algorithms to support three main functions:

1. Provide quality control assurance for spirometry.
2. Provide interpretation of the spirometry results.
3. Suggest a diagnosis, which may include a combination of spirometry results and clinical history.

The EAG note that a combination of valid spirometry and specific test results may lead to diagnosis, so may be inextricably linked or difficult to clearly discriminate in the evidence, such as when people with normal spirometry results are discharged (no disease). The EAG have therefore provided clarification on the following outcomes:

- **Accuracy of interpretation of spirometry**: included evidence pertaining to the accuracy of interpretation of spirometry results only, such as correct recognition of spirometry pattern (obstructive, restrictive, normal). The EAG considered that this outcome related to the performance of the technologies to interpret spirometry results, which may be independent of the final clinical diagnosis. For example, some patients may still receive a diagnosis of asthma based on clinical presentation, examination or other test results, such as blood eosinophils or fractional exhaled nitric oxide (FeNO), even where spirometry results are considered normal.
- **Accuracy of initial diagnosis**: included evidence pertaining to the accuracy of the technologies in correctly interpreting the overall clinical diagnosis, which may include spirometry or clinical details used by the technology algorithm to inform a diagnosis. The EAG note that some technologies may be used for people with an existing diagnosis to identify if they have been given an incorrect diagnosis and treatment (false positives); this has been considered by the EAG for the included technologies. In such cases where the spirometry result could not be isolated from other clinical details or related directly to the diagnosis, the EAG reported these results within the accuracy of initial diagnosis outcome for each technology.

Terminology

This early value assessment (EVA) focuses on technologies that support the interpretation of spirometry measurements. The American Thoracic Society (ATS) and European Respiratory Society (ERS) standardisation guidance defines spirometry as “a physiological test that measures the maximal volume of air that an individual can inspire and expire with maximal effort” (Graham et al. 2019).

Spirometry testing is recommended in NICE guidance to support diagnosis of asthma, COPD, and idiopathic pulmonary fibrosis (IPF, which is a type of ILD). Lung disease can be referred to as:

- restrictive, where people struggle to breathe in (such as ILD, which includes IPF); or
- obstructive, where people struggle to breathe out (such as asthma and COPD).

Other lung conditions, including respiratory infections such as pneumonia and lung cancer, which is the third most common cancer in the UK, are out of scope for this EVA.

Several measurements of volume or flow as a function of time may be used to describe a person’s lung capability: the most commonly reported include the forced expiratory volume in 1 second (FEV1) and forced vital capacity (FVC). Spirometry testing is operator dependent in terms of the usability of the results, as outlined in the Final Scope. The ATS/ERS guidance (Graham et al. 2019) structures quality in terms of the number of measurements and their repeatability, with grades issued separately for FEV1 and FVC (see Table 1). Separate values are available for children aged 6 years or younger. The repeatability sets taken before and after using a bronchodilator (drugs that cause the widening of the air passages of the lungs) are graded separately. The aim is always for grade A testing and results, however this is not always possible for patients and so lower grades, including the recently added U

grade, are acknowledged to be clinically useful. The ATS/ERS guidance emphasises the importance of the interpreter's clinical judgement for all grades lower than A. For further details relating to the measurements taken during spirometry and the use of bronchodilators during testing, please refer to Section 3 in the Final Scope.

Table 1: ATS/ERS Quality grading system for FEV1 and FVC

Grade	Number of measurements	Repeatability: age >6 years
A	≥3 acceptable	Within 0.150 litre
B	2 acceptable	Within 0.150 litre
C	≥2 acceptable	Within 0.200 litre
D	≥2 acceptable	Within 0.250 litre
E	≥2 acceptable	>0.250 litre
	Or 1 acceptable	Not applicable
U	0 acceptable and ≥1 usable	Not applicable
F	0 acceptable and 0 usable	Not applicable

In line with current NICE Guidance (NICE NG115), patients diagnosed with COPD typically have an FEV1/FVC ratio of less than 70%. The Global Initiative for Chronic Obstructive Lung Disease (GOLD, 2018) provides classification for COPD disease severity, which is based on the severity of the airflow limitation using a patient's post-bronchodilator FEV1 measurement. There are four classifications:

- GOLD 1: Mild, FEV1 greater than or equal to 80% predicted.
- GOLD 2: Moderate, FEV1 between 50% and 79% predicted.
- GOLD 3: Severe, FEV1 between 30% and 49% predicted.
- GOLD 4: Very severe, FEV1 less than 30% predicted.

The EAG considered clinical or economic evidence in patients with COPD with any disease severity status.

The EAG note that across the published literature, there may be different terms used for a specialist who has received specific pulmonary or respiratory training, including pulmonologist, pulmonary specialist, respiratory physician or respiratory physiologist. The EAG have used the specific specialist title as reported by each source.

2. Technologies

Six technologies from six manufacturers that support the quality assessment or interpretation of spirometry measurements have been included in this EVA. A brief summary of these technologies is included in Table 2, this has been derived from information found in the Final Scope and company supplied requests for information (RFI). The EAG note that two companies (Medical International Research (MIR) and NDD) did not provide a response to the standard RFI documents for their technologies (MIR Spiro and EasyOne Connect respectively) for this topic; therefore, information for those technologies was obtained from the scope and from the public domain.

As of August 2025, as indicated in the Final Scope, all six of the technologies had regulatory approval (five as class IIa and one as class I medical devices under either the EU Council Directive 93/42/EEC or EU Regulation 2017/745). Four technologies are Software as Medical Devices (SaMD) and do not come with hardware but require hardware to complete testing (ArtiQ.Spiro, EasyOne Connect, LungHealth, MIR Spiro). Three technologies were registered on the Public Access Registration Database (LungHealth, MIR Spiro, NuvoAir). Two companies (LungHealth and NuvoAir) stated they meet the Digital Technology Assessment Criteria (DTAC) and one company (Clario) advised that DTAC evaluation was in progress. One company (Monitored Therapeutics) advised they do not have DTAC.

Three companies (Clario, LungHealth and NuvoAir) have stated that their technologies are currently in use in the NHS, and one company (Monitored Therapeutics) stated that their technology is not currently used in the NHS.

The six technologies in scope of this assessment can be broadly categorised into two types of algorithm, see Table 2.

- Two technologies apply a *rules-based algorithm* only (broadly speaking, using sets of prewritten rules that are defined fixed values which act as triggers and notify users when input data meets those rules). The EAG note that the "rules" may vary between technologies and are dependent on which standard the companies have developed their rules upon, for the purposes of this assessment those rules are primarily ATS and ERS thresholds; a full breakdown by technology is shown in Table 2.

- Four technologies apply an *AI-derived algorithm* (using prewritten rules to make decisions and solve problems based on an algorithm that has been trained on relevant data to interpret and analyse inputs). Additional information regarding training and validation has been summarised by the EAG in Appendix C. In a previous assessment (GID-HTE10059 Artificial intelligence (AI) technologies to aid opportunistic detection of vertebral fragility fractures: Early Value Assessment) undertaken by the EAG, two local AI experts advised the EAG of the following in relation to regulations and best practices concerning the use of AI products for medical or clinical use:

    - AI technologies intended for medical or clinical use must disclose their training dataset, information workflow and validation approach as part of regulatory compliance.

    - AI technologies will be required to demonstrate they meet the DTAC, and the supplier should expect to provide a completed Data Protection Impact Assessment (DPIA).

    - Significant changes to the algorithm that could affect clinical impact, patient safety or change their regulatory classification require either a new submission or variation of the regulatory approval. All model

changes require performance validation and clinical risk assessment.

The EAG note that the technologies may all integrate into the diagnostic pathway differently (such as by setting):

- ArtiQ.Spiro is a software only technology used in a clinic setting.
- LungHealth is a computer-guided consultation software only technology used in a clinic setting (including conducting remote consultations).
- MIR Spiro is a software component compatible with MIR spirometers that can be used in a clinic- or home-based setting.
- NuvoAir contains both hardware and software to conduct home-based spirometry with remote clinical oversight.
- GoSpiro contains both hardware and software and can be used in the home and in a clinical setting.
- EasyOne Connect is a software component compatible with NDD spirometers that can be used in a clinic- or home-based setting.

From information provided by companies and from company websites, the EAG note that technologies included in this assessment:

- May involve a fixed AI algorithm (an AI or deep learning algorithm which has been reviewed by a notified body and released as a commercial product). Further updates to this “fixed” state require a review by the notified body. Typically, fixed algorithms do not learn or adapt to data that it processes during commercial use.
- Require internet access.
- Require a device to display and or receive results.

- Are to support and aid the clinician in reporting, that is, they will not be used autonomously without human interpretation. The EAG note that a comment was made during stakeholder consultation around the particular importance of this, and the expertise of the clinician, when the technology does not include clinical history taking in its algorithm.

- Each technology reports findings in a different manner as summarised in Table 2.

Clario confirmed that ArtiQ.Spiro is an algorithm focused on the interpretation of spirometry, with a separate algorithm, ArtiQ.QC providing feedback on the quality of the spirometry test, therefore the EAG have considered evidence for both technologies in line with the inclusion criteria set out above and in the EAG Protocol (2025). Furthermore, Clario confirmed that the algorithm used for interpreting spirometry results is the same in ArtiQ.Spiro and ArtiQ.PFT software, therefore have considered evidence relating to ArtiQ.PFT where results for spirometry interpretation have been reported exclusively.

The EAG also note that 2 technologies (ArtiQ.Spiro, GoSpiro) offer scores for the highest probability for diagnosis, with the highest scoring being referred to as the *preferred diagnosis*. Where other probability scores for diagnosis are considered, such as consideration of the top two highest probability scores, this was often referred to a *differential diagnosis.* At stakeholder consultation, ArtiQ.Spiro stated that it only provides physiological interpretation and quality feedback for children, and does not provide disease suggestions.

One respondent noted during stakeholder consultation that LungHealth does not interpret the quality of spirometry performed, and that data is inputted during the computer guided consultation. that the stakeholder noted that responsibility remains on the user to make sure that the results inputted are reliable (that is repeatable and reproducible) for accurate interpretation.

At stakeholder consultation, one consultee stated that spirometry for non-diagnostic purposes was less common in primary and community care settings. They stated that NuvoAir may be helpful for use in secondary care

and disease monitoring; however the EAG notes that this is out of scope of this early value assessment.

Additional detailed information relating to each device can be found in Appendix C.

Table 2: Technology Summary

Device (Company) [Previous Name]	Indications	Type of technology	Type of algorithm (as claimed by company)	Use of patient clinical history	Outputs	Performs Quality Assessment	Additional features (as claimed by company)
ArtiQ.Spiro [ArtiQ.PFT] (Clario)	Patients aged between 5 and 96 years, that have undergone pulmonary function testing used in, used in primary care and community diagnostic settings	SaMD, with no graphical user interface, combining two sub-components one on quality assessment and one on spirometry interpretation. Integrated with 2 spirometer providers Vitalograph (Spirotrac6 software) and MedChip (SpiroConnect software).	AI & Rules based (ATS/ERS)	No	A quality report and an interpretation report. Accessed by clicking a button in the spirometer software	Report provides feedback on the quality of the measurement according to ATS/ERS guidelines and artificial intelligence to analyse the shape of spirometry curves and detect abnormalities	Uses artificial intelligence to calculate disease probabilities (including asthma, COPD, ILD, normal and unidentified) and options for next steps to support the diagnostic process. This feature is only available for an adult population. For children, the technology provides only physiological interpretation and quality feedback. Provides automated physiological interpretation of PFTs as per ERS/ATS guidelines
LungHealth (LungHealth)	Patients aged 18 years and over for COPD 12 years and over for asthma used in primary care (GP practices)	SaMD - No physical device	AI & Rules based (NICE/BTS/GOLD/SIGN)	Clinical history is taken as part of the review and progress through a series of screens to build the history and symptoms to support test results	Interprets raw spirometry results and presents into a patient report. Person conducting test enters raw values (FEV1 and FVC)	Interprets spirometry results (historic/current) when they are entered and provides an output	Can be used in face-to-face consultations or delivered remotely from the patient via a video consultation platform
*MIR Spiro (Medical International Research, MIR)	Patients aged 5 years and over. Setting NR	SaMD - No physical device Compatible with Minispir, Spirobank II Basic, Spirobank II Smart, Spirodoc, Spirolab spirometers	Rules based - Spirometry (ATS/ERS 2005 + 2019 update; ISO 23747: 2015; ISO 26782: 2009), Oximetry (ISO 80601-2-61:2017), and others	NR	Reports exportable in wide variety of file types	Advises when tests have not met criteria and provides feedback	For children, interactive animations are shown during spirometry tests to keep them engaged and ensure the results are accurate and reliable
*EasyOne Connect (NDD)	Patients aged 4 years and over. Setting NR	SaMD - No physical device but compatible with EasyOne devices (Air, PC, Sky, Pro, Pro LAB and Mobile)	Rules based (ATS/ERS)	NR	NR	Real-time coaching & feedback	For children, interactive animations are shown during spirometry tests to keep them engaged and ensure the results are accurate and reliable. 2 available animations for FVC and 1 animation for FVL
GoSpiro (Monitored Therapeutics)	Patients over 5 years age, used in in physician's offices, clinics, and home settings to conduct basic lung function and spirometry testing.	Medical device with firmware that collects and displays data with cloud-based interface. GoSpiro Body, Vertical Turbine Assembly & Charging Station. Comes with an app on a tablet. Requires internet access.	AI & Rules based (ATS/ERS)	Algorithms on the cloud server can use a patient's clinical history alongside the results from the lung function testing to provide a clinical diagnostic impression or follow up care to be considered	Data is transmitted and displayed locally on a tablet, smartphone or computer Clinicians can log onto the cloud server from anywhere to view data, data trends, add their interpretation, sign and print reports	Provides feedback to patient and personnel after each measurement if it was suboptimal with reasons and improvements	Avatar assisted technology guides patients through the spirometry manoeuvres without needing a highly skilled technician guiding the session and Patients are informed by the avatar if they made an error, and how to correct the error on the next measurement.
NuvoAir (NuvoAir) [Air Next]	Air Next spirometer is intended to be used by competent adults that have been trained by a healthcare professional to perform spirometry and monitor diseases affecting the respiratory system. A competent adult can assist a child who is aged 5 years and over to perform a spirometry test for use in both clinical and home/personal settings	Hand-held spirometry, a patient-facing app to track trends and a web-based portal for clinicians to view results and reports. Air Next Spirometer, Disposable Turbine, User Manual, Cotton Bag, 2 x AAA Alkaline Batteries. Requires companion app connected via Bluetooth	AI (Interpretation of spirometry results) & Rules based (ATS 2019)	No	Real-time spirometry date in a web-based portal for clinicians Viewable immediately for the patient in the companion app spirometry assessment reports are made available in the portal within 48 hours of a patient completing the home assessment and can be downloaded as a PDF to be uploaded to a client record	Companion app provides instructions	Service includes postage of devices directly to individuals (at home)

*Note: Information on MIR Spiro and EasyOne Connect has been taken from the scope and company websites exclusively
Abbreviations: AI, Artificial Intelligence; ATS, American Thoracic Society; BTS, British Thoracic Society; COPD, Chronic Obstructive Pulmonary Disease; ERS, European Respiratory Society; FEV1, forced expiratory volume in 1 second; FVC; Forced Vital Capacity , FVL; Flow Volume Loop ,GOLD, Global Initiative for Chronic Obstructive Lung Disease; ILD, Interstitial lung disease; IPF, Idiopathic Pulmonary Fibrosis; ISO, International Organization for Standardization; NR, Not Reported; NSIP; nonspecific interstitial pneumonitis, PFTs, Pulmonary function tests; SaMD, Software as Medical Device; SIGN, Scottish Intercollegiate Guidelines Network

3. Clinical context

For a detailed description of the conditions and their respective diagnostic pathways included in this EVA, please refer to the Final Scope.

According to the 2023 Asthma and Lung UK Saving Your Breath report, lung disease is the third leading cause of death in the UK (Foster 2023). This includes COPD, asthma and pneumonia. Asthma and COPD cost the NHS £9.6bn in direct costs each year (3.4% total NHS expenditure) (Foster 2023). Earlier detection and accurate diagnosis of lung conditions, such as asthma or COPD, could reduce critical illness and unplanned urgent treatment thus reducing overall burden to the NHS. Access to objective diagnostic testing was restricted during the COVID-19 pandemic and has not recovered, which is contributing to wide variation in service across the UK (Doe et al. 2023a). Foster (2023) also noted that increasing uptake of objective lung function tests, such as FeNO and spirometry in primary care could save the NHS approximately £160m per year through optimising treatment and reducing exacerbations.

NHS clinicians and commissioners have highlighted the potential value for the use of technologies that support the quality assurance or interpretation of spirometry in primary care to support the restart or quality improvement of services or to drive a reduction in workload (Doe et al. 2023a). Furthermore, the 2023 Diagnosing the Problem: Right Test Right Time Asthma and Lung UK Report noted that the use of algorithms to support quality assurance in spirometry performance and interpretation may have the potential to provide a more cost-effective service (Warren 2023).

3.1 National guidelines

Spirometry is recommended by NICE to support diagnosis of lung conditions such as asthma, COPD and IPF. The point at which spirometry testing is carried out differs by condition as well as patient characteristics, such as age.

- **Asthma**: there is no single objective test to diagnose asthma and a combination of tests may be needed for most people alongside a their clinical history and assessment (NICE QS25). The diagnostic pathway for people with suspected asthma is captured within NICE, British Thoracic Society (BTS) and Scottish Intercollegiate Guidelines Network (SIGN) guideline NG245, which states:
    - For people aged 16 years and older, bronchodilator reversibility (BDR) with spirometry should be considered where a diagnosis cannot be made from either blood eosinophils measurement or FeNO test.
    - For people aged between 5 and 16 years, BDR with spirometry should be considered where diagnosis cannot be made from FeNO testing.

    Where BDR with spirometry is delayed or not available, peak expiratory flow variability should be used. NG245 states that "objective testing in children under 5 years is not recommended because it is difficult for children in this age group to do the tests and there are no good reference standards".

- **COPD**: for people aged over 35 years who present with a risk factor (generally smoking or a history of smoking) and one or more symptoms of COPD (exertional breathlessness, chronic cough, regular sputum production, frequent winter 'bronchitis', or wheeze), post-bronchodilator spirometry testing should be used to support diagnosis (NICE NG115, NICE QS10, Global Initiative for Chronic Obstructive Lung Disease 2024).

- **IPF**: for people aged 18 years and older with suspected IPF, lung function testing (spirometry and gas transfer) should be performed alongside a detailed history, clinical examination, blood tests, chest X-ray and thorax CT imaging (NICE CG163).

NHS England sets out commissioning standards for spirometry, which highlight the need for restoration of good quality and accessible spirometry within clinical pathways following the COVID-19 pandemic (NHS England 2024). This mirrors the call for standards and identification of issues affecting the quality of test results as far back as 2010 (Global Initiative for Chronic Obstructive Lung Disease 2024).

3.2 Spirometry certification

As noted in the Final Scope, it is recommended that all staff performing or interpreting spirometry in the UK should be certified and registered on the Association for Respiratory Technology and Physiology (ARTP) Spirometry Register, which helps staff to ensure good clinical practice (Warren 2023). Such accreditation is not mandatory and often not reimbursed by employers. The 2023 Diagnosing the Problem: Right Test, Right Time report by Asthma and Lung UK highlighted a need to provide funding and time to support staff with completion of certification and maintaining registration to ensure good professional practice and quality-assured spirometry. The 2024/25 review of Integrated Care Systems (ICSs) by Asthma and Lung UK reported the number of staff on the ARTP Spirometry Register ranged from 6 to 127 per ICS, although the proportion of staff with accreditation was not reported. Additionally, the ARTP publish a breakdown of accredited staff in the NHS, by region and by Integrated Care System in the Spirometry Register. From this register, as of August 2025, there were 2,368 active registrants in NHS of England of which 1,947 were in primary care; 129 in Wales (of which 106 in primary care), 61 in Northern Ireland (49 in primary care) and 20 in Scotland (4 in primary care), The use of the technologies to support quality assurance or interpretation of spirometry has been accepted as potentially helpful for primary care services (Doe et al. 2023a; Warren 2023), however its potential impact on the recommendation for accreditation of staff remains unknown and beyond scope of this EVA.

3.3 Setting

For lung conditions such as asthma and COPD, diagnosis is usually done at the GP surgery or Community Diagnostic Centre (CDC). As of August 2024, there were 165 operational CDCs in England of 170 approved sites (NHS England 2024). Locations include shopping centres, university campuses and sports venues, with an aim to increase accessibility to tests which for many previously required a hospital visit.

The 2024/25 review of Integrated Care Systems by Asthma and Lung UK reported nearly 85% (27 of 32) Integrated Care Systems commission adult spirometry services in primary care, however only 25% (8 of 32) had sufficient spirometry capacity to meet demand of new referrals and to address any waiting list backlog. Ten ICSs did not respond to the survey, therefore the commissioning of adult spirometry services for all 42 services is unknown. Additionally, data for the number of referrals for spirometry is poor and not centrally collected or held; where reported, the number of spirometry tests performed during the financial year ranged from 2,500 to 28,742. Many spirometry services are commissioned through a Locally Enhanced Service. Two Experts suggested that the range of spirometry referrals per GP practice per year is broad from fewer than 5 to over 300, with an average of 74 referrals per practice (Appendix D1). The review also found that only 12 ICS responders commission spirometry for children, of which only 3 report sufficient capacity to meet the demand of new referrals.

The Experts noted that waiting times for spirometry can vary by setting and area, with waiting times for spirometry in primary care ranging from 4 weeks to 12 months (Appendix D1). Two Experts also noted that the proportion of people given a provisional diagnosis who receive treatment while awaiting spirometry differs by condition and age (Appendix D1):

- 40 to 80% of people aged 16 years and older with suspected asthma;
- 40% of children aged between 5 and 15 years with suspected asthma;

- 30% of people with suspected COPD.

Furthermore, two Experts noted that between 10% and 50% of people with suspected asthma may receive a diagnosis without having spirometry (Appendix D1).

Some of the technologies included in this EVA offer the opportunity to conduct spirometry testing at home, either through sending the technology directly to the patient (GoSpiro, NuvoAir) or the portability of the device enabling NHS staff to conduct home-based assessments (GoSpiro, MIR Spiro, EasyOne Connect). One technology (NuvoAir) offers an exclusively home-based spirometry diagnostic service overseen by independent physiologists. The EAG is unaware of any ICSs commissioning exclusively home-based spirometry diagnostic services. The Experts noted that home-based spirometry was typically used for monitoring rather than diagnosis and that test quality may depend on the patient's experience performing spirometry (Appendix D2). The GOLD guide identifies patient technique as the main reason for inconsistent readings (Global Initiative for Chronic Obstructive Lung Disease, 2025). Two Experts also noted that spirometry is typically done at home alongside supervision from a healthcare professional and one noted that the potential throughput of patients having home-based spirometry for diagnosis may depend on location, such as rural or urban areas (Appendix D1). The EAG acknowledge that home-based assessment may offer access to spirometry where services are limited or unavailable or offer an opportunity to perform opportunistic testing when a patient is symptomatic, which may offer particular benefits for diagnosing asthma (Daines et al. 2019; Levy 2016).

3.4 Routinely collected data in the NHS

Nationally collected datasets are available for conditions in scope of this EVA, however their use for collecting or reporting data relevant to this assessment is mostly limited to outcomes following diagnosis and as such may be helpful for addressing long-term evidence gaps following implementation. For

example, registry and audit data often capture data beyond primary care diagnostic services including secondary care diagnosis and management or hospital admissions. Some may provide clinical context, such as the proportion of patients who undergo spirometry as part of their diagnostic assessment.

3.4.1 Registry datasets

Asthma

- For patients with severe asthma (accounting for between 5 to 10% of UK asthma patients), a UK Severe Asthma Registry is available.

COPD

- In 2019, NICE recommended a general practice register for COPD (NICE IND190), however the EAG have been unable to identify a national registry for COPD.

ILD

- The Interstitial Lung Disease Registry, which is held by the British Thoracic Society, was established in 2013 to capture national longitudinal data for patients with IPF and sarcoidosis and expanded in February 2023 to include all fibrosing ILDs. Diagnosis of IPF and entry into the registry requires a multidisciplinary team with expertise in ILD (British Thoracic Society Report, 2025), so will typically be done outside of primary care services.

3.4.2 National audits

The National Respiratory Audit Programme (NRAP) has been commissioned by the Healthcare Quality Improvement Partnership as part of the National Clinical Audit and Patient Outcomes Programme and currently covers England and Wales. NRAP is a development of The National Asthma and Chronic Obstructive Pulmonary Disease Audit Programme (NACAP) to include respiratory services beyond the original focus on COPD and asthma.

The NACAP Drawing breath report (2023) included information from 708 eligible services (primary care data is for Wales only).

Asthma

Based on NACAP data gathered across 2021 to 2022, 61.8% of hospitals had access to both FeNO and spirometry for asthma diagnosis in children and young people, and 43.9% of adults diagnosed with asthma were recorded as having an objective diagnostic measurement (not further defined) in primary care.

The BTS audit reports contain potentially relevant detail but are several years old. The last BTS audit of paediatric patients (aged over 12 months) with asthma was published in 2016 containing data on 5,443 records on hospital admissions received between 1 November 2015 and 30 November 2015 (Paton 2016). Children were included if they had a primary diagnosis of wheezing or asthma rather than just asthma to include those with no previous history. Authors noted that children are often diagnosed without any objective measurements, with no detail provided regarding the proportion who have undergone spirometry as part of their diagnostic evaluation. The last BTS audit of adult patients with asthma was published in 2017 containing data on 4,258 records on hospital admissions received between 1 September 2016 and 31 October 2016 (Scott 2017). Asthma was recorded as a previous diagnosis in 89% of records and of these only 42% were based on objective testing (not further defined).

COPD

The NACAP Drawing breath report (2023) figures for primary care in Wales (no data available for England) stated that only 1.9% of adults with COPD had the gold standard post-bronchodilator spirometry for diagnosis. A 2025 audit by the Royal College of Physicians as part of the NRAP reported that 49% of patients hospitalised with COPD had a quality-assured spirometry informing the diagnosis. This figure was increasing, from 43% between 2021 and 2022 and from 46% between 2022 and 2023.

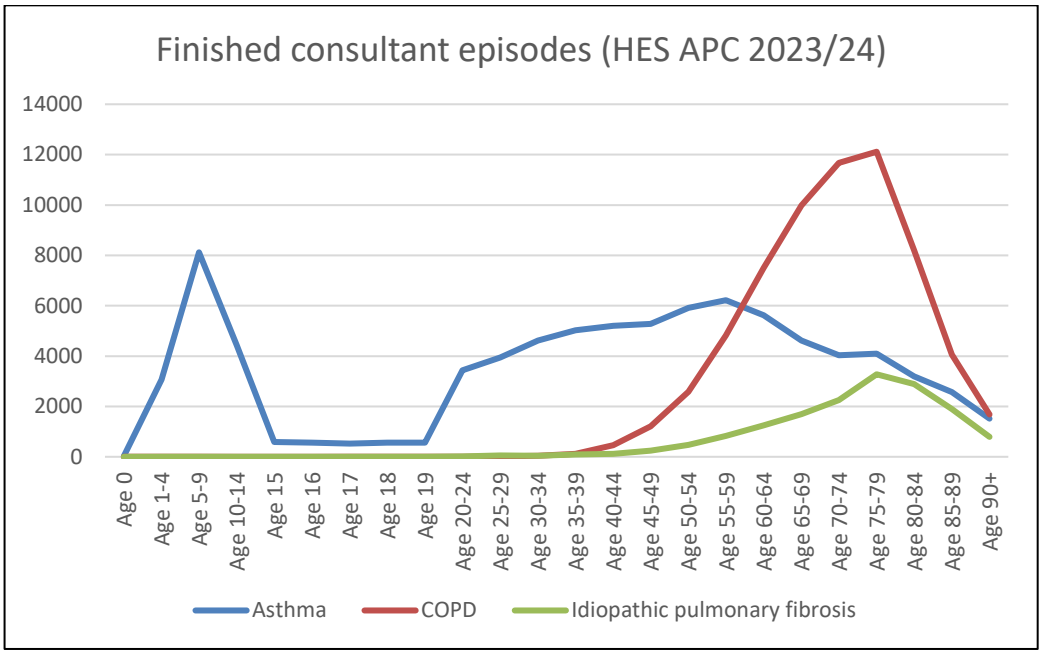
3.4.3 Hospital Admitted Patient Care Activity

Routinely collected data within Hospital Episode Statistics does not currently capture detail regarding the technologies used during diagnosis, however it does give an idea of scale of hospital resource usage in England for patients with specific diagnoses. For example within the 2023/24 financial year, Hospital Admitted Patient Care Activity reports released by NHS Digital stated the following totals of finished consultant episodes with a primary diagnosis (ICD10 code):

- Asthma unspecified (J45.9) was the primary reason for admission documented in 57,132 hospital admissions (89.4% of which were emergency admissions), with a median length of stay of 1 day (mean 2.6) and mean age of 44 years (with clear separation between admissions in children and adults, see Figure 1) .
- COPD with an acute exacerbation (J44.1) was the primary reason documented in 34,555 admissions (98.7% of which were emergency admissions), with a median length of stay of 3 days (mean 4.4 days), and mean age 71 years.
- IPF (J84.1) was the primary reason documented for 8,282 admissions (66.5% of which were emergency admission), with a median length of stay of 5 days (mean 8.7 days) and mean age of 74 years.

These aggregated national data summaries are limited (noting that patients can attend hospital more than once), however Figure 1 illustrates the difference in patient age between disease groups.

Figure 1: Finished consultant episodes (from Hospital Episode Statistics Admitted Patient Care database) from 2023/24 with primary diagnosis code of asthma, COPD and IPF



Hospital Accident and Emergency Activity dataset recorded 130,674 attendances with a primary code of Asthma (SNOMED CT code: 195967001). However, the clinical coding team within the Newcastle upon Tyne Hospitals NHS Foundation Trust advised that they do not code patient notes in A&E and outpatient settings, which potentially limits using this dataset for future research associated with the scope of this EVA.

3.5 Equality issues

Equality issues and considerations for this EVA are described in the Equalities Impact Assessment (2025) alongside the scope. Contraindications associated with each of the technologies are reported (where available) in Appendix C1.

Digital health technologies need internet access via a computer, tablet, or smartphone and a level of digital literacy. This may limit access for people who are unfamiliar with or do not have the required technology. Some people may be disadvantaged by living in a geographical area with poor digital coverage; limiting access to the technology or virtual assessments via video

calls (which need higher bandwidth). Patients may also have limited access to devices and data plans because of socioeconomic circumstances. Overcoming these barriers may increase resource costs.

Patient-facing digital health technologies may be unsuitable for those with cognitive impairment, problems with manual dexterity or learning disabilities. Some patients may also require assistance from a carer or advocate to use the technology, such as conducting home-based spirometry with remote clinical support or responding to detailed clinical questions. Therefore, the use of a technology should be carefully considered by the referring practitioner using shared decision-making with the patient.

Digital health technologies should also be available in an appropriate range of languages either within the app or via device settings to enable access for those with a preferred primary language. Some people may prefer to be seen face-to-face as they may struggle to engage with a digitally enabled programme. Patient-facing digital health technologies should ensure their programme is accessible for those with visual or hearing impairments.

4. Clinical evidence

In order to identify clinical evidence associated with the technologies included, the EAG developed a search strategy.

4.1 Search strategies and study selection

The search strategies were developed using search terms from the original NICE scoping searches, from manufacturer websites, from bibliographic database thesauri (for example, Medline MeSH and Embase EMTREE) and from literature identified during the initial scoping searches.

Search strategies were developed by one of the EAG's information specialists for Embase and peer reviewed by a second information specialist. The strategy was translated, adapted and run on 01 September 2025 independently on Embase (OVID), Medline (OVID), Cochrane Library CDSR/CENTRAL (systematic reviews and trials, Wiley), International HTA

Database (INAHTA) to identify peer reviewed studies and conference abstracts. For completed and ongoing clinical trials, a trial registry and a multi-registry search platform were searched (Clinicaltrials.gov, ICTRP), Appendix A1. No time or language limits were applied in the search. Clinical effectiveness searches retrieved a total of 256 results, of which, 222 remained after deduplication.

For completeness, for technologies where the software and spirometers had distinct names (such as, where the spirometer names would not be included in the search to avoid finding unmanageable numbers of irrelevant results), the EAG conducted additional targeted searches (on Embase and Clinicaltrials.gov) using the names of the spirometers (EasyOne and Spirobank) and qualified with terms designed to locate a narrower selection of results with the greatest likelihood of relevance (Appendix A1). This provided an additional 77 results, of which only 1 paper was deemed relevant to the scope. Due to the low number of relevant hits to the decision problem of this EVA, the EAG took a pragmatic approach and decided not to conduct a systematic literature search related EasyOne or Spirobank spirometers.

4.2 Included and excluded studies

The title and abstract of the 299 results of the main and targeted searches were sifted according to the final scope (NICE, 2025) by a single reviewer (RP, Appendix A2), with a 10% sample also checked by a second reviewer (PL). A total of 245 items were subsequently excluded. Full papers were retrieved and reviewed by two reviewers (RP, PL), of which 16 were included. An additional 14 papers were identified through hand searching or provided by the companies. A total of 30 publications were included, Table 3. Excluded studies and reasons for exclusion have been tabulated in Appendix A5.

Table 3: Characteristics of included studies (N=30)

				Population characteristics									Outcomes reported														
#	Technology	Author (reference, year; page) [Study type]	Study design (n=patients or clinicians); Country	Undiagnosed	Diagnosed	Adult	Paediatric	Asthma	COPD	ILD	Comparator	Setting	Access to spirometry and number of 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	Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment	Mortality	Morbidity	Clinician confidence in performing and interpreting spirometry and making diagnosis	Clinician acceptability, ease of use and satisfaction	Health-related quality of life	Patient and carer acceptability, views, experience and satisfaction
1	ArtiQ.Spiro (Clario)	Adams (Practice Nurse, 2024; 22-25) [Editorial]	Prospective cross-sectional cohort (n=51 patients, n=2 clinicians), UK	✓	✓	✓	-	✓	✓	-	Interpretation spirometry without AI	Primary care	-	✓	-	✓	-	✓	-	-	-	-	✓	-	-	-
2	ArtiQ.Spiro (Clario)	De Vos (Eur Resp J, 2023) [Abstract]	Qualitative cross-sectional cohort (GPs, n=NR) Belgium	✓	-	✓	-	-	✓	-	None	Primary care	-	-	-	-	-	-	-	-	-	-	-	✓	-	-
3	ArtiQ.Spiro (Clario)	Doe (NEJM AI, 2025a;8)	RCT superiority study (n=234 clinicians randomised, 133 completed; n=50 patient datasets) UK	-	✓‡	✓	-	✓	✓	✓	Spirometry grading and interpretation without AI support. Reference standard: pulmonologist expert panel	Primary care (secondary care reference standard)	-	✓	✓	-	-	✓	-	-	-	-	✓	-	-	-
4	ArtiQ.Spiro (Clario)	Doe (Am J Resp Crit Care Med, 2025b; 211) [Abstract]	Qualitative focus group (n=9) UK	✓	-	✓	-	✓*	✓*	✓*	None	Primary care	-	-	-	-	-	-	-	-	-	-	-	-	-	✓
5	ArtiQ.Spiro (Clario)	Hayes (PCRS, 2025b) [Poster]	Service evaluation (n=NR) UK	✓	-	✓*	✓*	✓*	✓*	✓*	Standard care (spirometry without AI support)	Primary care	✓	-	-	✓	-	-	-	-	-	-	✓	✓	-	-
6	ArtiQ.Spiro (Clario)	Maes (Am J Resp Crit Care Med, 2024;A1461) [Abstract]	Diagnostic concordance (n=NR) Belgium	✓	-	✓*	✓*	✓*	✓*	✓*	Diagnosis by expert panel (3 pulmonologists) without use of AI software	Primary care (secondary care reference standard)	-	-	-	-	-	✓	-	-	-	-	-	-	-	-

				Population characteristics									Outcomes reported													
#	Technology	Author (reference, year; page) [Study type]	Study design (n=patients or clinicians); Country	Undiagnosed	Diagnosed	Adult	Paediatric	Asthma	COPD	ILD	Comparator	Setting	Access to spirometry and number of 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	Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment	Mortality	Morbidity	Clinician confidence in performing and interpreting spirometry and making diagnosis	Clinician acceptability, ease of use and satisfaction	Health-related quality of life	Patient and carer acceptability, views, experience and satisfaction
7	ArtiQ.Spiro (Clario)	Polaris (ERS Conference, 2025) [Abstract, supplied by Company]	Retrospective comparative cohort (n=248) UK	-	✓‡	✓	-	-	✓	-	Spirometry interpretation by ARTP-registered clinicians	NR (COPD diagnostic pathway)	-	-	-	-	-	✓	-	-	-	-	-	✓	-	-
8	ArtiQ.Spiro (Clario)	Ray (Am J Resp Crit Care Med, 2022; A4884) [Abstract]	Retrospective comparative cohort (n=109) UK	-	✓‡	✓	-	-	-	✓	Standard care	NR (AI applied to UK Biobank dataset)	-	-	-	-	✓	✓	-	-	-	-	-	-	-	-
9	ArtiQ.Spiro (Clario)	Smets (Am J Resp Crit Care Med, 2025; A3652) [Abstract]	Service evaluation (n=19 patients, n=1 healthcare assistant conducting spirometry) UK	✓	-	✓*	✓*	✓*	✓*	✓*	None	Primary care	-	✓	-	-	-	-	-	-	-	-	-	-	-	-
10	ArtiQ.Spiro (Clario)	Sunjaya (ERJ Open Res, 2025)	Blinded diagnostic accuracy (n=1,113 patients) UK	-	✓‡	✓*	-	✓*	✓*	✓*	Spirometry grading and interpretation by pulmonologist expert panel (n=3, reference standard)	Primary care dataset (secondary care reference standard)	-	-	-	-	-	✓	-	-	-	-	-	-	-	-
11	ArtiQ.Spiro (Clario)	Willaert (Int Prim Care Resp Group, 2023) [Abstract]	Qualitative semi-structured interview (n=8 GPs) Belgium	✓*	✓*	-	✓*	✓*	✓*	✓*	None	Primary care	-	-	-	-	-	-	-	-	-	-	✓	-	-	-
12	GoSpiro (Monitored Therapeutics)	Rydberg (COPD, 2023; 437-443)	Pilot prospective non-comparative cohort (n=12) US	-	✓	✓	-	-	✓	-	None	Home-based spirometry	-	-	-	-	-	-	-	-	-	-	-	-	-	✓
13	LungHealth (LungHealth)	Angus (Am J Resp Crit Care Med, 2019; A3338)	Service evaluation (n=741) UK	-	✓	✓	-	-	✓	-	None	Primary care	-	-	✓	-	-	✓	-	-	-	-	-	-	-	-

				Population characteristics									Outcomes reported													
#	Technology	Author (reference, year; page) [Study type]	Study design (n=patients or clinicians); Country	Undiagnosed	Diagnosed	Adult	Paediatric	Asthma	COPD	ILD	Comparator	Setting	Access to spirometry and number of 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	Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment	Mortality	Morbidity	Clinician confidence in performing and interpreting spirometry and making diagnosis	Clinician acceptability, ease of use and satisfaction	Health-related quality of life	Patient and carer acceptability, views, experience and satisfaction
		[Abstract]																								
14	LungHealth (LungHealth)	Angus (Am J Resp Crit Care Med, 2017; A1736) [Abstract]	Service evaluation (n=2,704) UK	-	✓	✓	-	-	✓	-	None	Primary care	-	-	-	-	-	✓	-	-	-	-	-	-	-	-
15	LungHealth (LungHealth)	Angus (Prim Care Resp J, 2012; 425-430)	Service evaluation (n=293 patients, 18 nurses) UK	-	✓	✓	-	-	✓	-	None	Primary care	-	-	✓	✓	-	✓	-	-	-	-	-	✓	-	-
16	LungHealth (LungHealth)	Chakrabarti (Prim Care Resp Med, 2025a; 12)	Service evaluation (n=5,221) UK	-	✓	✓	-	-	✓	-	None	Primary care	-	-	✓	-	-	✓	-	-	-	-	-	-	-	-
17	LungHealth (LungHealth), ArtiQ.Spiro (Clario) [Mixed intervention]	Chakrabarti (PCRS, 2025d) [Poster, submitted by Company]	Service evaluation (n=103) UK	✓	✓	✓	-	✓	✓	-	None	Primary care	-	-	✓	-	-	✓	-	-	-	-	-	-	-	-
18	LungHealth (LungHealth)	Chakrabarti (PCRS, 2024; 296) [Poster]	Service evaluation (n=847) UK	-	✓	✓	-	-	✓	-	None	Primary care	-	-	-	-	-	✓	-	-	-	-	-	-	-	-
19	LungHealth (LungHealth)	O'Driscoll (Nat Serv for Health Improv, 2024) [Poster]	Service evaluation (n=1,661) UK	-	✓	✓	-	-	✓	-	None	Primary care	-	-	-	-	-	✓	-	-	-	-	-	-	-	-
20	LungHealth (LungHealth)	Thompson (Thorax, 2013a; S71) [Abstract]	Service evaluation (n=2,000) UK	-	✓	✓	-	-	✓	-	None	Primary care	-	-	-	-	-	✓	-	-	-	-	-	-	-	-

				Population characteristics									Outcomes reported													
#	Technology	Author (reference, year; page) [Study type]	Study design (n=patients or clinicians); Country	Undiagnosed	Diagnosed	Adult	Paediatric	Asthma	COPD	ILD	Comparator	Setting	Access to spirometry and number of 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	Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment	Mortality	Morbidity	Clinician confidence in performing and interpreting spirometry and making diagnosis	Clinician acceptability, ease of use and satisfaction	Health-related quality of life	Patient and carer acceptability, views, experience and satisfaction
21	LungHealth (LungHealth)	Thompson (Am J Resp Crit Care Med, 2013b; A2829) [Abstract]	Service evaluation (n=417) UK	-	✓	✓	-	-	✓	-	None	Primary care	-	-	-	-	-	✓	-	-	-	-	-	-	-	-
22	MIR Spiro (MIR)	Lusuardi (Chest, 2006; 844-852)	RCT (n=333 patients enrolled, n=104 GPs enrolled, 74 GPs completed trial) with parallel observational study (n=2,055 patients enrolled, n=236 GPs) Italy	✓	-	✓	-	✓	✓	-	GP diagnosis without spirometry, specialist diagnosis (reference standard)	Primary care (secondary care reference standard)	-	-	✓	✓	-	✓	-	-	-	-	-	✓	-	-
23	MIR Spiro (MIR)	Castro (Ther Adv Resp Dis, 2024; 1-17)	Prospective non-comparative study (n=108) US	-	✓	✓	✓	✓	-	-	None	Home-based spirometry	-	-	-	-	-	-	-	-	-	-	-	-	-	✓
24	MIR Spiro (MIR)	Khatoon (medRxiv, 2025) [Pre-print]	Qualitative semi-structured interview (n=15) UK	✓	-	✓	-	✓	-	-	None	Home-based spirometry	-	-	-	-	-	-	-	-	-	-	-	-	-	✓
25	NuvoAir (NuvoAir)	Coughlin (Am J Resp Crit Care Med, 2021; A3188) [Abstract]	Qualitative survey (n=18 patients or carers) UK	-	✓	-	✓	✓	-	-	None	Home-based spirometry	-	-	-	-	-	-	-	-	-	-	-	-	-	✓
26	NuvoAir (NuvoAir)	Gray (RCPCH, 2026, AiC) [Provided by Company]	[redacted]	[redacted]							[redacted]	[redacted]														
27	NuvoAir (NuvoAir)	Kocks (Research Square, 2023; 1-27)	Cross-sectional cohort, mixed methods (n=140 patients, n=28 healthcare professionals)	-	✓	✓†	-	✓	✓	-	Spirometry grading and interpretation by expert panel	Home-based spirometry	-	✓	-	-	-	-	-	-	-	-	✓	-	-	✓

				Population characteristics									Outcomes reported													
#	Technology	Author (reference, year; page) [Study type]	Study design (n=patients or clinicians); Country	Undiagnosed	Diagnosed	Adult	Paediatric	Asthma	COPD	ILD	Comparator	Setting	Access to spirometry and number of 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	Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment	Mortality	Morbidity	Clinician confidence in performing and interpreting spirometry and making diagnosis	Clinician acceptability, ease of use and satisfaction	Health-related quality of life	Patient and carer acceptability, views, experience and satisfaction
		[Pre-print]	Netherlands, Sweden								(n=3, reference standard)															
28	NuvoAir (NuvoAir)	Parrott (Eur Resp J, 2023; PA1583) [Abstract]	Retrospective non-comparative cohort (n=40) UK	✓‡	✓‡	✓	-	✓	-	-	None	Home-based spirometry	-	✓	-	-	-	✓	✓	-	-	-	-	-	-	-
29	NuvoAir (NuvoAir)	Robshaw (Eur Resp J, 2024; OA4592) [Abstract]	Service evaluation (n=120) UK	✓	✓	✓	-	✓	-	-	None	Home-based spirometry	-	✓	-	-	-	✓	✓	-	-	-	-	-	-	-
30	NuvoAir (NuvoAir)	Tuli (BTS, 2025 AiC) [Provided by Company]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Abbreviations: AI, Artificial intelligence; ARTP, Association for Respiratory Technology & Physiology; COPD, chronic obstructive pulmonary disease; FeNO, Fractional exhaled nitric oxide; ILD, Interstitial lung disease; NR, not reported; RCT, randomised control trial

Key: * people having spirometry in primary care to inform a diagnosis, EAG assumed this includes people with suspected asthma, COPD, or ILD and includes children where otherwise not explicitly excluded; † 16 years and older; ‡ clinician or software diagnosis interpretation using a retrospective dataset

5. Clinical evidence review

5.1 Quality appraisal of studies

To fully consider evidence for all technologies in scope and to meet the appraisal objectives, the EAG broadened the scope to include populations with an existing diagnosis of asthma, COPD or ILD. This resulted in the inclusion of a total of 30 pieces of evidence, which used ArtiQ.Spiro (N=11), GoSpiro (N=1), LungHealth (N=9), MIR Spiro (N=3), and NuvoAir (N=6). Of which, seven studies exclusively reported qualitative outcomes relevant to the scope relating to clinician or user perspectives for the technologies. No relevant evidence was identified by the EAG for the EasyOne Connect technology. This approach included evidence for these technologies when applied to a population with a higher disease prevalence and may include people who have performed spirometry previously, which may impact the baseline quality of the test. Additional evidence was also included for NuvoAir, which captured its use for home-based spirometry for monitoring of asthma or COPD. Once again, this may include people who have undertaken spirometry in a clinical setting prior to performing home-based testing using remote clinical oversight or instruction, which may impact the quality or validity of the test.

When considering evidence exclusively in an undiagnosed population in scope of this decision problem, the EAG identified 8 studies for 3 technologies:

- ArtiQ.Spiro was included in 5 studies (De Vos et al. 2023; Doe et al. 2025b; Hayes et al. 2025b; Maes et al. 2024; Smets et al. 2025). Three studies were set in the UK, with the remaining two studies set in Belgium.

- MIR Spiro was used in 2 studies (Lusuardi et al. 2006, Khatoon et al. 2025), which included a randomised controlled trial (RCT) set in Italy and UK qualitative study respectively.

- [redacted]

The EAG note that the EVA outcomes focus on the use of fixed algorithms (do not learn or adapt to data processed during commercial use) including those based on international guidelines to correctly identify spirometry patterns, test quality or interpretation. Therefore, the algorithm function may not fundamentally differ between diagnosed or undiagnosed populations and the ability for the technologies to correctly interpret spirometry or suggest a diagnosis may be independent of any existing clinical diagnosis. However, the impact of higher baseline disease prevalence or use in non-spirometry-naive people on the outcomes in scope remain unclear from the current evidence base. Two studies in exclusively diagnosed populations were also included for GoSpiro and MIR Spiro, which captured evidence for patient usability only, which was an outcome not considered to differ significantly between diagnosed or undiagnosed populations.

The EAG extracted study characteristics for the 30 included sources of evidence, Appendix A4. The EAG note that the availability and setting of evidence, in addition to the populations captured, differs between the technologies in scope, Table 3:

- ArtiQ.Spiro is used in a clinic setting, with evidence captured within a UK NHS or Belgian primary and secondary care settings. This was the only technology to have evidence in asthma, COPD and restrictive lung disease populations.

- LungHealth evidence exclusively comprised of non-comparative service evaluations in a UK NHS primary care setting although predominantly used during clinical reviews of adults diagnosed with COPD. Only one poster included a mixed population with adults with suspected or diagnosed COPD or asthma (Chakrabarti et al. 2025b) although also used a mixed intervention with spirometry conducted using ArtiQ.Spiro; no study included a paediatric population.

- MIR Spiro has evidence available reporting its use in a clinic setting for diagnosis (adults with suspected asthma or COPD) and patient usability evidence when used in a home setting (adults and children with diagnosed asthma).

- NuvoAir evidence is largely focused on adults and children with a diagnosed lung condition (COPD or asthma) who can perform valid spirometry at home in the Netherlands, Sweden or UK.

- GoSpiro evidence was limited to one full publication set in the US reporting on patients' ease of use of the spirometer at home in people diagnosed with COPD.

- No evidence in scope of this EVA was identified for EasyOne Connect or the compatible EasyOne spirometers.

Evidence was lacking in an undiagnosed population for GoSpiro, LungHealth, and [redacted] No comparative evidence in scope was available for LungHealth and GoSpiro and limited for NuvoAir. Additionally, there was a lack of longitudinal evidence for all technologies, likely reflective of the scope of this EVA focusing on diagnosis only.

In line with the EVA process and methods, formal critical appraisal was not conducted for the included evidence, rather, a summary of the evidence quality has been presented here. The included evidence comprises predominantly abstract, poster, editorial, pre-print formats or submitted in confidence by the companies, which may lack peer review. Several studies are surveys, questionnaires, or focus group based and such design is subject to volunteer bias. Reporting of study funding was poorly reported across the included evidence and many sources of evidence included company-employed co-authors. Most of the evidence was set in a UK NHS setting with evidence including broad sample sizes, ranging from 8 to 5,221 (sample size was not reported in 3 studies).

Study designs were a mixture of qualitative and quantitative methods, and UK NHS service evaluations dominated the included evidence. RCT evidence was available for two technologies ArtiQ.Spiro, (UK NHS, Doe et al. 2025a) and MIR Spiro (Italy, Lusuardi et al. 2006). The EAG note that the latter RCT reports the use of the MIR Spirobank Office, which the EAG assume is a predecessor version and may not be reflective of the current software and technology iterations in scope (unable to confirm because of a lack of company engagement). The EAG also notes a significant proportion of protocol violations in Lusuardi et al. (2006); authors reported analyses for the intention-to-treat and a per-protocol populations with power calculations on the case series at different levels.

The RCT for ArtiQ.Spiro aligns well with the scope of the decision problem. The study was set in a UK NHS setting and compared diagnostic prediction performance for primary care clinicians with and without access to the software against a secondary care expert pulmonologist panel reference standard. The EAG contacted three of the authors who were NICE-ratified topic experts for this EVA on 23 September 2025 to request access to this data, with data received academic-in-confidence on 07 October 2025 (Appendix D4). Using this data, the EAG have been able to calculate sensitivity and specificity for primary care clinicians with and without access to ArtiQ.Spiro. However, the EAG note that the sample sizes were small; with the greatest disease prevalence represented in the dataset was COPD with 20 patients and asthma with 6 patients. The EAG consider that a real-world evidence study with a larger sample size would provide additional evidence for how the technology works in NHS practice and show whether the results from the RCT are seen in a real-world context.

5.2 Results from the evidence base

5.2.1 ArtiQ.Spiro (Clario)

Eleven studies (seven abstracts, two full publications, one editorial, and one poster) were available for ArtiQ.Spiro, eight of which were set in the UK and

three in Belgium. No evidence was identified exclusively in a paediatric asthmatic population. There was no long-term follow up reported across the studies (single timepoint only) notably, long-term outcomes relating to morbidity, mortality, health-related quality of life, and hospital exacerbations or the number of referrals to secondary care for diagnosis were not captured.

Diagnostic accuracy of initial diagnosis

Mixed adult population

Doe et al. (2025a) reported results from a UK RCT (SPIRO-AID trial, NCT05933694) where 133 participants (primary care clinicians who refer for, perform, or interpret spirometry) were randomised to review 50 retrospective spirometry records with or without ArtiQ.Spiro AI support (Table 4). The reference diagnosis standard was a diagnosis by two respiratory physiologists without access to the AI software reports. Technical quality grading and spirometry pattern reference standards were also provided by an expert respiratory physiologist. Participant data were included where at least 35 of the 50 spirometry records had been reviewed within 8 weeks of consent and the primary outcome was the number of correct diagnostic predictions expressed as a percentage of the 50 spirometry records. Secondary outcomes were the differential diagnosis prediction performance (where the participant's preferred or second most likely preferred diagnosis matched the reference diagnosis), grading of technical quality of FEV1 and FVC, pattern interpretation against reference. Self-rated confidence with diagnosis, technical quality grading and pattern interpretation was also assessed. Reference diagnoses included a sample of 40% COPD, 20% normal spirometry, 10% asthma, 10% ILD, 10% other obstructive, 10% other disease or unidentifiable category. Authors report a statistically higher mean (SD) preferred diagnosis prediction performance in the AI intervention group compared with the control group with 58.7% (7.0%) and 49.7% (16.6%) respectively, p=0.001. This outcome was unchanged when adjusting for covariates or assessing missing data not missing at random. Similar mean

differences were seen regardless of role (GP or non-GP) or inclusion on the National Spirometry Register.

The UK service evaluation by Adams et al. (2024) compared diagnosis with and without the use of ArtiQ.Spiro software in 51 spirometry sessions. Authors noted that ArtiQ.Spiro matched the interpretation in 86% cases, 10% mismatch, and 4% data missing. In two of the five mismatched cases, the clinicians assessed AI to be incorrect based on the patient's clinical history, clinicians changed the diagnosis to likely ILD based on the AI suggestion in two cases, and one case was inconclusive (Table 4). Authors noted that in several cases the physiological pattern was reported instead of an actual clinical diagnosis, however the number of cases and whether this was clinician or ArtiQ.Spiro interpretation or level of agreement were not reported.

Maes et al. (2024) compared diagnoses made by GPs from 6 Belgian primary care practices performing and interpreting spirometry with ArtiQ.Spiro AI support with an expert panel of three pulmonologists. In 77% of cases, GPs agreed with the diagnosis proposed by the technology (Table 4).

Table 4: Summary of spirometry diagnosis level of agreement (ArtiQ.Spiro)

Study; Location	Population	Intervention	Comparator	Level of agreement [SD] (95%CI)
Adams (2024) [Editorial]; UK	Mixed (adults with suspected or confirmed asthma or COPD)	ArtiQ.Spiro AI diagnosis	ARTP-accredited nurse or GP diagnosis	86% (NR)
Doe (2025a); UK	Mixed (adults with asthma, ILD or COPD)	Primary care diagnosis with ArtiQ.Spiro	Primary care diagnosis without ArtiQ.Spiro, two pulmonologists without access to AI software (reference standard)	Mean **preferred diagnostic** prediction performance: • Intervention: 58.7 [7.0]% • Comparator: 49.7 [16.6]% • Mean difference: 9.0 (4.5 to 13.3)%, p=0.001 Mean **differential diagnostic** prediction performance: • Intervention: 74.1 [7.8]%

Study; Location	Population	Intervention	Comparator	Level of agreement [SD] (95%CI)
				• Mean difference: 7.3 (3.0 to 11.7)%
Maes (2024) [Abstract]; Belgium	Mixed (adults and children with suspected asthma, ILD or COPD)	ArtiQ.Spiro AI diagnosis	Three pulmonologists, access to AI support unclear	82% (NR)
		ArtiQ.Spiro AI diagnosis	GP diagnosis	77% (NR)
Polaris (2025) [Abstract]; UK	Adults with COPD	ArtiQ.Spiro diagnosis	Interpretations by ARTP-registered clinicians	Negative predictive value = 0.942

Abbreviations: AI, artificial intelligence; ARTP, Association for Respiratory Technology and Physiology; CI, confidence interval; COPD, chronic obstructive pulmonary disease; ILD, interstitial lung disease; NR, not reported; SD, standard deviation

Patients with suspected COPD

The EAG used the data supplied academic-in-confidence by the SPIRO-AID trial team to calculate the sensitivity and specificity of primary care clinicians with and without access to ArtiQ.Spiro against an expert panel reference standard (Appendix D4). The EAG note that the sample size was small, with 20 of 50 patients in the dataset diagnosed with COPD. The EAG note that [redacted]

The UK retrospective, blinded, diagnostic validation study by Sunjaya et al. (2025) reported diagnostic accuracy of ArtiQ.Spiro in 1,113 patients from a primary care spirometry dataset including COPD, asthma, ILD, normal and other obstructive disease subgroups (Table 5). Authors reported sensitivity and specificity for the software's preferred diagnosis (category with highest probability score) and differential diagnosis (top two categories with highest probability scores). Of the 543 patients diagnosed with COPD, ArtiQ.Spiro had a preferred diagnosis sensitivity of 84.0% (95% confidence interval, CI 80.6 to

87.0), specificity of 86.8% (95% CI 83.8 to 89.5), and accuracy of 85.4% (95% CI 83.2 to 87.5) compared with the reference diagnosis (consensus of expert pulmonologists with access to primary and secondary care medical notes and results of relevant investigations). When applying the differential diagnosis from ArtiQ.Spiro the sensitivity increased to 90.6% (95%CI 87.8 to 92.9) and the specificity decreased to 75.6% (95% CI 71.9 to 79.1). When ArtiQ.Spiro software was applied using FEV1 and FVC ratio of less than 0.7 to identify COPD, the sensitivity remained unchanged at 90.6% (95% CI 87.8 to 92.9), however the specificity reduced further to 67.5% (95% CI 63.5 to 71.4). Authors reported that the AI software performed better in current or ex-smokers, those with a BMI less than 30, and cases where there was direct consensus of trial experts. Agreement between ArtiQ.Spiro and a reference diagnosis had an overall Cohen's Kappa agreement coefficient of 0.477, and the most common misclassification for COPD patients was asthma (8.29%) followed by ILD (5.16%), with 1.47% being classed as normal. The quality of spirometry (determined by the acceptable quality of FEV1 and FVC measurements) in COPD cases did not impact the classification accuracy of the AI software.

The Company shared an abstract (Polaris, 2025) that was accepted for presentation at the ERS Conference with the EAG (Table 4). ArtiQ.Spiro was applied to spirometry data from a cohort of 248 patients, who attended the direct-access COPD diagnostic pathway in Glasgow, UK. Results were compared with diagnostic interpretations by ARTP-registered clinicians. There were high levels of agreement between 'normal' AI interpretation and 'normal' clinician-reported spirometry results and diagnoses (negative predictive value = 0.942), which the EAG assume refers to there being no sign of COPD or other lung conditions, Table 4. No information was given on agreement of COPD diagnoses between AI interpretation and reference diagnosis.

Adults with suspected asthma

The EAG used the data for the SPIRO-AID trial team to calculate the sensitivity and specificity of primary care clinicians with and without access to

ArtiQ.Spiro against an expert panel reference standard (Appendix D4). The EAG note that the sample size was small, with 6 of 50 patients in the dataset diagnosed with asthma. Similar to COPD, the EAG note that [redacted]

Sunjaya et al. (2025) reported of the 107 patients diagnosed with asthma (reference diagnosis of expert consensus), ArtiQ.Spiro had a sensitivity of 55.1% (95% CI 45.2 to 64.8), specificity of 86.9% (95% CI 84.6 to 88.9), and accuracy of 83.8% (95% CI 81.5 to 85.9). Most common misclassifications for the ArtiQ.Spiro for asthma patients was COPD (16.82%) followed by ILD (14.02%), with 5.61% being classed as normal (Table 5).

Adults with suspected ILD

Sunjaya et al. (2025) reported of the 249 patients diagnosed with ILD (reference diagnosis of expert consensus), ArtiQ.Spiro had a sensitivity of 75.1% (95% CI 69.3 to 80.3), specificity of 85.9% (95% CI 83.4 to 88.1), and accuracy of 83.5% (95% CI 81.2 to 85.6). Most common misclassifications for the ArtiQ.Spiro for ILD patients was asthma or classed as normal with 7.63% for each respectively (Table 5).

The UK retrospective cohort study by Ray et al. (2022) applied ArtiQ.PFT spirometry algorithm to a dataset from the UK Biobank. The dataset included 109 patients who had ILD as a cause of death and who had spirometry performed within seven years prior to their death with no diagnosis of ILD on the day of the spirometry test. Patient characteristics (sex, age, height, weight, race, smoking status) and spirometry data were used as inputs into the AI software. ArtiQ software noted that ILD was the highest probable disease detected in 26.6% (29 of 109) patients including where spirometry parameters were within normal limits of the ATS/ERS 2005 interpretation guidelines.

Table 5: Summary of diagnostic accuracy (ArtiQ.Spiro, Sunjaya et al. 2025)

Note: the study used two pulmonologists without access to the AI technology with adjudication by a third as the reference standard.

Prevalence, %	Sensitivity, % (95%CI)	Specificity, % (95%CI)	Accuracy, % (95% CI)	PPV, % (95% CI)	NPV, % (95% CI)	AUROC, (95% CI)
COPD: 48.8 (543/1,113), PD	84.0 (80.6 to 87.0)	86.8 (83.8 to 89.5)	85.4 (83.2 to 87.5)	85.9 (83.1 to 88.3)	85.1 (82.4 to 87.4)	0.914 (0.896 to 0.930)
COPD: 48.8 (543/1,113), DD	90.6 (87.8 to 92.9)	75.6 (71.9 to 79.1)	82.9 (80.6 to 85.1)	78.0 (75.3 to 80.4)	89.4 (86.6 to 91.7)	NR
Asthma: 9.6 (107/1,113), PD	55.1 (45.2 to 64.8)	86.9 (84.6 to 88.9)	83.8 (81.5 to 85.9)	30.9 (26.1 to 36.1)	94.8 (93.7 to 95.8)	0.814 (0.790 to 0.836)
Asthma: 9.6 (107/1,113), DD	83.2 (74.7 to 89.7)	60.5 (57.4 to 63.6)	62.7 (59.8 to 65.6)	18.3 (16.7 to 20.1)	97.1 (95.7 to 98.1)	NR
ILD: 22.4 (249/1,113), PD	75.1 (69.3 to 80.3)	85.9 (83.4 to 88.1)	83.5 (81.2 to 85.6)	60.5 (56.2 to 64.7)	92.3 (90.6 to 93.7)	0.900 (0.990 to 0.916)
ILD: 22.4 (249/1,113), DD	85.9 (81.0 to 90.0)	77.2 (74.3 to 80.0)	79.2 (76.7 to 81.5)	52.1 (48.8 to 55.4)	95.0 (93.3 to 96.3)	NR
Normal: 2.7 (30/1,113), PD	33.3 (17.3 to 52.8)	96.0 (94.7 to 97.1)	94.3 (92.8 to 95.6)	18.9 (11.5 to 29.4)	98.1 (97.6 to 98.5)	0.871 (0.850 to 0.891)
Unidentified: 8.5 (95/1,113), PD	2.1 (0.3 to 7.4)	98.7 (97.8 to 99.3)	90.5 (88.6 to 92.1)	13.3 (3.4 to 40.2)	91.5 (91.3 to 91.8)	0.744 (0.717 to 0.769)
Other obstructive disease: 8.0 (89/1,113), PD	0 (no positive cases identified by AI)	98.6 (97.7 to 99.3)	90.8 (88.9 to 92.4)	0 (no positive cases identified by AI)	91.9 (91.9 to 92.0)	0.580 (0.551 to 0.610)

Abbreviations: AI, artificial intelligence; AUROC, area under the receiver operating characteristic curve; CI, confidence interval; COPD, chronic obstructive pulmonary disease; DD, differential diagnosis (top two categories with highest probability score with AI); ILD, interstitial lung disease; NPV, negative predictive value; NR, not reported; PD, preferred diagnosis (top category with highest probability score with AI); PPV, positive predictive value

Accuracy of interpretation of spirometry

Doe et al. (2025a) reported that for the 67 clinicians who had access to ArtiQ.Spiro correct spirometry pattern interpretation was made in 64.9% cases compared with 65.8% in 66 clinicians who did not use the technology. The authors also reported a COPD subgroup analysis with correct spirometry pattern interpretation in 53.7% cases when using ArtiQ.Spiro software compared with 56.3% without use of the technology. The EAG note that the wide confidence intervals show no significant difference between arms for the main group analysis or the subgroup analysis, Table 6.

Table 6: Summary of accuracy of interpretation of spirometry (ArtiQ.Spiro)

Study; Location	Intervention, correct interpretation % (SD)	Comparator, correct interpretation % (SD)	Mean difference (intervention – comparator), % (95% CI)
Doe (2025a); UK	64.9 (18.9)	65.8 (19.8)	-0.9 (-5.7 to 7.5)
Doe (2025a) (COPD subgroup analysis); UK	56.3 (22.9)	53.7 (20.4)	-2.6 (-10.1 to 4.8)

Abbreviations: CI, confidence interval; SD, standard deviation

Quality of spirometry performance

Two comparative studies reported that the quality of spirometry performance was improved when using ArtiQ.Spiro (Table 7), however each assessed quality differently. The UK RCT by Doe et al. (2025a) reported an increase in the proportion of measurements with correct grading of 5.0% for FEV1 and 10.8% for FVC respectively when the ArtiQ.Spiro technology was used. The UK service evaluation by Adams et al. (2024) compared clinician diagnosis with and without the use of ArtiQ.Spiro software in 51 spirometry sessions. Authors noted that ArtiQ.Spiro agreed with the clinician quality assessment in 94% of cases, however no further detail was given.

The UK non-comparative prospective cohort abstract by Smets et al. (2025) reported the use of a single non-accredited (National Spirometry Register) healthcare assistant (HCA) performing spirometry over a period of four months in a primary care setting using ArtiQ. A total of 31 sessions were

evaluated; spirometry was conducted on 19 patients and bronchodilator reversibility (BDR) testing was performed on 12 patients. For quality (Grade A being highest quality and Grade C lowest), FEV1 was rated as Grade A in 29 sessions (93.5%) and FVC was rated as Grade A in 22 sessions (71.0%) and Grade B in 6 sessions (19.4%) with a mean of 3 trials to achieve optimal quality standards. However, as this is a non-comparative study it is unclear whether this is an improvement over standard care.

Table 7: Summary of number of quality spirometry tests (ArtiQ.Spiro)

Study; Location	Study design (n, number of patients)	Intervention, clinician interpretation with AI support, % [SD]	Comparator, clinician interpretation without AI support, %
Doe (2025a); UK	RCT (n=50)	Correct grading of FEV1: 68.3 [3.5] Correct grading of FVC: 54.7 [8.7]	Correct grading of FEV1: 63.3 [7.3] Correct grading of FVC: 43.9 [10.0]
Smets (2025) [Abstract]; UK	Prospective cohort (single arm) (n=19)	FEV1: • Grade A: 93.5 (29/31) • Grade B: NR FVC: • Grade A: 71.0 (22/31) • Grade B: 19.4 (6/31)	N/A

Abbreviations: AI, artificial intelligence; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; N/A, not applicable; NR, not reported; SD, standard deviation

Access to spirometry and the number of tests performed

The UK service evaluation by Hayes et al. (2025b) reported a revised model of spirometry delivery, with testing performed by a Band 3 Respiratory Care and Support Worker supported by AI-assisted interpretation (ArtiQ.Spiro) and supervised by ARTP certified staff. The poster reported an increase in testing capacity of 75 tests per month (Table 8) and that patient waiting times had improved (before and after not reported) and stated that full backlog resolution projected within 8 months (backlog volume was not quantified).

Table 8: Summary of number of spirometry tests performed (ArtiQ.Spiro)

Study; Location	Study design	Intervention, tests per month with AI support	Comparator, tests per month without AI support	Difference, tests per month
Hayes (2025b) [Poster]; UK	Service evaluation	375	300	75

Abbreviations: AI, artificial intelligence; NR, not reported

Time to perform and interpret spirometry

Two UK service evaluations reported the impact of the use of ArtiQ.Spiro on appointment times and staffing. Hayes et al. (2025b) reported that appointment times were reduced from 60 minutes to 45 minutes, which released a total of 206 hours of a Band 6 or 7 nurse and 90 hours of a Band 4, however no further detail was provided, including a time period over which these time savings were observed. Adams et al. (2024) reported that the mean (SD) time for ARTP accredited GPs and nurses to evaluate spirometry results decreased from 10.6 (4.1) mins to 5.6 (5.6) mins ($p<0.001$) by using ArtiQ.Spiro, Table 9.

Table 9: Summary of time to perform and interpret spirometry (ArtiQ.Spiro)

Study; Location	Intervention, mins (SD)	Comparator, mins (SD)	Clinical time released
Adams (2024) [Editorial]; UK	Time to evaluate spirometry results: 5.6 (5.6)	Time to evaluate spirometry results: 10.6 (4.1)	NR (p-value reported <0.001)
Hayes (2025b) [Poster]; UK	Appointment time: 45 (NR)	Appointment time: 60 (NR)	• 206 hours Band 6 or 7 • 90 hours of Band 4

Abbreviations: NR, not reported; SD, standard deviation

Time-to-diagnosis

No study reported on time-to-diagnosis in a prospective cohort. The UK retrospective diagnostic validation study Ray et al. (2022) applied the ArtiQ spirometry algorithm (within the ArtiQ.PFT software) to a UK biobank dataset of 109 people who had ILD as a cause of death and spirometry performed

within 7 years prior to their death and that at the time of the spirometry measurement no diagnosis of ILD was made. By retrospectively applying the ArtiQ algorithm to these spirometry measurements, it suggested ILD as a diagnosis in 26.6% patients (29 of 109). This implies that ILD could have been diagnosed sooner if ArtiQ had been used to interpret the spirometry (assumed missed in standard care).

Number of referrals to secondary care for a diagnosis

No studies were identified that reported this outcome.

Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment

No studies were identified that reported this outcome.

Mortality

No studies were identified that reported this outcome.

Morbidity

No studies were identified that reported this outcome.

Clinician confidence in interpreting spirometry results and making diagnosis

Four studies reported on clinician confidence using ArtiQ.Spiro, however all measured and reported this outcome differently, Table 10:

- Doe et al. (2025a) reported a non-statistically significant increase in primary care clinician (those who refer to, perform or interpret spirometry) confidence in making a diagnosis, FEV1 and FVC technical grading and identification of spirometry pattern (normal, airflow obstruction, possible restriction or non-specific pattern, or possible mixed disorder) using a 10-point visual analogue scale (VAS) with (n=67) and without (n=66) ArtiQ.Spiro AI support.

- Adams et al. (2024) reported that there was no change in clinician (ARTP-accredited GP or nurse) confidence in spirometry interpretation using a 5-point Likert scale when using ArtiQ.Spiro.

- The UK poster by Hayes et al. (2025b) reported survey results (number of participants not reported) from GPs (40%), practice nurses (37%), nurse practitioners or other professionals (11.5% respectively) during a service evaluation of ArtiQ.Spiro. Of which, 40% noted that ArtiQ.Spiro influenced their decision making and 33% found the AI-generated disease suggestion slightly useful, 32% also felt extremely confident or confident with the accuracy of the AI report.

- The semi-structured interview study by Willaert et al. (2023) reported feedback on the use of AI software (assumed relevant to ArtiQ.Spiro due to author affiliation) for performing and interpreting spirometry. Eight GPs from three Belgian GP practices recognised the need for more objective findings before making a diagnosis or altering therapies and spirometry was noted to be valuable for this with AI-based software felt to be a diagnostic support. Concerns about unfamiliarity with the spirometry procedure and limited time and resources were considered barriers to implementation.

Table 10: Summary of clinician confidence (ArtiQ.Spiro)

Study; Location	Study design	Intervention (SD)	Comparator (SD)	Mean difference (95% CI)
Adams (2024) [Editorial]; UK	Prospective cross-sectional cohort (n=2 clinicians, 1 ARTP-accredited nurse and 1 GP undertaking ARTP accreditation)	Confidence in diagnosis with AI support (5-point Likert scale; 1=not confident, 5=extremely confident): • 3.9 (1.3)	Confidence in diagnosis without AI support: • 4.0 (1.0)	NR
Doe (2025a); UK	Qualitative focus group	Confidence in diagnosis with AI support (10-point VAS;	Confidence in diagnosis without AI support:	• 0.31 (-0.31 to 0.95)

Study; Location	Study design	Intervention (SD)	Comparator (SD)	Mean difference (95% CI)
	(n=9 primary care clinician)	0 not confident, 10 very confident): • 6.44 (1.89) Confidence in FEV1 and FVC technical grading: • 6.60 (1.89) Confidence in identifying spirometry pattern: • 6.54 (1.82)	• 6.13 (1.86) Confidence in FEV1 and FVC technical grading: • 6.31 (2.36) Confidence in identifying spirometry pattern: • 6.39 (1.93)	• 0.29 (-0.44 to 1.02) • 0.15 (-0.69 to 0.79)
Hayes (2025b) [Poster]; UK	Service evaluation (n=NR; mixture of GPs, practice nurses, nurse practitioners, other professionals)	Felt confident or extremely confident with accuracy of AI report: 32%. Sometimes used AI to influence decision-making: 40% Found AI-generated disease suggestion slightly useful: 33%	NR	NR
Willaert (2023) [Abstract]; Belgium	Semi-structured interviews (n=8 GPs from 3 practices)	Spirometry in general was recognised as having value in objective testing before making a diagnosis or altering therapies. AI-based software was felt to be supportive of this.	NR	NR

Abbreviations: AI, artificial intelligence; ARTP, Association for Respiratory Technology and Physiology; CI, confidence intervals; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; NR, not reported; SD, standard deviation; VAS, visual analogue scale

Clinician acceptability, ease of use, experience and satisfaction

Three studies reported on the acceptability, ease of use and satisfaction of using ArtiQ.Spiro, however each measured and reported this differently, Table 11:

- The qualitative study by De Vos et al. (2023) asked GPs in 18 Belgian general practices to rate the usefulness of ArtiQ.Spiro for quality assessment and diagnostic support for people with suspected COPD on a

5-point Likert scale, with results indicating scores of 4.13 and 4.01 respectively.

- The UK service evaluation by Hayes et al. (2025b) reported survey responses from a mix of clinical staff (number not reported) including GPs, practice nurses, nurse practitioners and other professionals regarding views of ArtiQ.Spiro when compared to a non-AI supported delivery model. Authors reported 20% of survey respondents agreed that ArtiQ.Spiro saved them time. Additionally, despite the non-AI supported model of delivery being deemed unsustainable, only 17% felt satisfied with the AI service as compared to the nurse-led model, additional training and support for how to interpret AI reports was felt to be needed to aid delivery. The poster also reported information regarding staffing: zero vacancies, sickness absence decreased 3% points, and morale was high. However, there was a lack of detail reported in the poster (for example the timings of these outcomes was unclear, and basement measurements prior to introduction of technology was not reported), which made it difficult to put these additional benefits of ArtiQ.Spiro into context.

- The UK concordance study abstract by Polaris (2025) reported that clinician user feedback on ArtiQ.Spiro was positive, highlighting its potential to enhance workflow efficiency. No other data was available.

Table 11: Summary of clinician feedback (ArtiQ.Spiro)

Study; Location	Study design	Key findings
De Vos (2023) [Abstract]; Belgium	Qualitative study (18 GP practices, n=NR)	Usefulness of ArtiQ.Spiro for quality assessment (5-point Likert scale): • 4.13 Usefulness of ArtiQ.Spiro for diagnostic support: • 4.01
Hayes (2025b) [Poster]; UK	Service evaluation (n=NR; mixture of GPs, practice nurses, nurse practitioners, other professionals)	• Satisfied with AI service compared with nurse-led model: 17% • Felt use of ArtiQ.Spiro saved time: 20% • Additional training and support for how to interpret AI reports was felt to be needed to aid delivery (not quantified).

Study; Location	Study design	Key findings
Polaris (2025) [Abstract]; UK	Concordance study	• User feedback was positive (not quantified), highlighting potential to enhance workflow efficiency.

Abbreviations: AI, artificial intelligence; NR, not reported;

Health-related quality of life

No studies were identified that reported this outcome.

Patient acceptability, ease of use, experience and satisfaction

The UK qualitative study by Doe et al. (2025b) obtained feedback from nine patients undergoing spirometry in primary care to explore the use of AI decision support software for spirometry interpretation. Themes included that AI is likely a positive addition to healthcare, however the human element of diagnosis and decision making should not be lost from clinical care, and clinicians should retain oversight of the report and diagnostic outcomes. Participants noted that there may be benefits (not stated) to speeding up the process for their spirometry results.

5.2.2 EasyOne Connect (NDD)

No evidence in scope of this EVA was identified for this technology nor provided by the company. In line with the inclusion criteria outlined in the EAG Protocol (2025) and Section 4.1 Search strategies and study selection, the EAG considered evidence for EasyOne spirometers (which are compatible with EasyOne Connect software). Unfortunately, no evidence meeting this eligibility was identified by the EAG.

5.2.3 GoSpiro (Monitored Therapeutics)

No publication was identified or submitted by the company reporting the impact of the use of GoSpiro software to support the diagnosis of COPD, asthma or ILD in any setting. One abstract (Podolanczuk et al. 2023) and one

editorial (Stenzler et al. 2019b) reported the reproducibility of FEV1 or FVC values using the GoSpiro spirometer when used in home-based setting compared with lab- or hospital-based setting in patients with an existing diagnosis of COPD or IPF. This evidence was excluded in line with the EAG approach outlined in the Protocol (2025) and Section 1, which excluded inter-comparisons of spirometer values or only reporting the quality of spirometry tests in a diagnosed population. Only one US pilot prospective non-comparative cohort study met the Scope of this EVA (Rydberg et al. 2023).

Patient acceptability, ease of use, experience and satisfaction

Rydberg et al. 2023 reported patient feedback on the use of GoSpiro spirometer for home COPD monitoring, where 45.5% of 12 respondents reported that the spirometer was mostly or extremely easy to use.

5.2.4 LungHealth (LungHealth Ltd.)

Nine UK service evaluations were available for LungHealth, no evidence was available exclusively in an undiagnosed population with suspected asthma, COPD or ILD. Only one poster, shared by the Company, included a mixed population with patients with and without an existing lung disease diagnosis (Chakrabarti et al. 2025d), however all patients underwent spirometry using ArtiQ.Spiro software and the LungHealth computer-guided consultation (mixed intervention). All studies included a single timepoint with no long-term follow-up. No comparative evidence in scope was identified. Outcomes captured in the evidence base were the number, accuracy and quality of spirometry tests, time to perform and interpret spirometry testing and diagnostic accuracy of initial diagnosis alongside clinician acceptability and training time. Additionally, diagnostic accuracy relating to the re-application of the technology to confirm an existing diagnosis was not reported.

Diagnostic accuracy of initial diagnosis

No comparative evidence was available for the performance of LungHealth compared with a reference standard, which means it has not been possible to determine the sensitivity and specificity of using LungHealth to inform a diagnosis, nor determine the accuracy of the algorithm interpretation against standard care. Furthermore, only one study included a mixed population of people with and without a diagnosed lung condition, which the company shared as a poster accepted for the Primary Care Respiratory Society Respiratory Conference 2025 (scheduled for 18 to 20 September 2025). LungHealth was used alongside ArtiQ Spiro software (mixed intervention) in 103 patients, as part of the Best Respiratory Evaluations And Treatments in Healthcare Efficiency (BREATHE) study (Chakrabarti et al. 2025d). Patients were either awaiting diagnostic spirometry for suspected COPD or had an existing diagnosis of COPD or asthma which was being reviewed (proportions not reported). Of the 103 patients assessed with LungHealth and ArtiQ.Spiro, 41 (39.8%) had a diagnosis of COPD. No comment was made on the remaining 62 patients. This presents the only evidence for use of LungHealth that includes a proportion of undiagnosed patients, however this is a mixed intervention and mixed population and lacks a reference standard to confirm the accuracy of diagnosis. The validity and generalisability of results from this study are therefore unknown.

The remaining eight studies included people with an existing diagnosis of COPD and reported the proportion who had their diagnosis changed; which ranged between 14.6% and 29.2%, Table 12. However, it is unclear whether the interpretation of spirometry results was the main factor for changing the diagnosis. No follow-up was available to determine the impact of the change in primary diagnosis and no comparison was available for any previous spirometry results or interpretation. The EAG also note that Chakrabarti et al. (2025a) reported that the spirometry results that did not meet the GOLD guidelines for COPD spirometry results were flagged by the LungHealth system, however only those who had COPD confirmed with spirometry underwent the full computer-guided consultation. Furthermore, O'Driscoll et al.

(2024) also reported 14.6% (243 of 1,661) patients who underwent LungHealth review has their diagnosis changed from COPD. However, authors also noted that remote clinical review of clinical records and historical spirometry traces identified that only 55.9% (3,850 of 6,892) on the COPD register from the 26 practices were deemed as meeting COPD diagnosis based on ARTP spirometry standards prior to being referred for a LungHealth review. The EAG therefore notes that a proportion of patients may be identified as misdiagnosed from clinical review alone. Given these limitations, the EAG is unable to comment on the validity and generalisability of result from these studies.

Table 12: Summary of changes in diagnosis (LungHealth)

Study; Location	Proportion with diagnosis change, %	Proportion of normal spirometry testing, %	Proportion of other lung disease diagnoses, %
Angus (2012); UK	COPD: 29.2 (69/236)	43.5 (30/69)	Restrictive lung function: 21.7 (15/69) Asthma: 17.4 (12/69) Cardiac problems: 14.5 (10/69) Bronchiectasis: 2.9 (2/69)
Angus (2017) [Abstract]; UK	COPD: 22.7 (614/2,704)	NR	NR
Angus (2019) [Abstract]; UK	COPD: 24.5 (181/741)	NR	NR
Chakrabarti (2025a); UK	COPD: 21.1 (1,104/5,221)	61.7 (681/1,104)	Restrictive lung function: 36.6 (404/1,104) Asthma: 1.7 (19/1,104)
Chakrabarti (2024) [Poster]; UK	COPD: 17.2 (146/847)	NR	NR
O'Driscoll (2024) [Poster]; UK	COPD: 14.6 (243/1,661)	NR	NR
Thompson (2013a) [Abstract]; UK	COPD: 23.0 (459/2,000)	NR	NR
Thompson (2013b) [Abstract]; UK	COPD: 19.0 (79/417)	NR	NR

Abbreviations: COPD, chronic obstructive pulmonary disease; NR, not reported

Accuracy of interpretation of spirometry

No comparative evidence was available to determine the accuracy of the spirometry pattern interpretation, Table 13. Four UK service evaluations reported spirometry interpretation, including spirometry pattern interpretation. Chakrabarti et al. (2025a) reported that 404 of 5,221 (7.7%) patients were identified as having restrictive lung function based on the spirometry pattern. Chakrabarti et al. (2025d; Figure 2) shows that of 103 patients; over 50 had normal spirometry, over 40 had obstructive spirometry, less than 10 patients had restrictive spirometry, and fewer than 5 patients showed a reversible pattern indicative of asthma. Angus et al. (2012) reported that LungHealth identified 45 of 236 (19.1%) patients who had spirometry did not have airflow obstruction (30 had normal and 15 had restrictive function). Angus et al. (2019) reported that LungHealth identified 181 of 741 (24.4%) patients did not have obstructive spirometry from spirometry records on the day or recent records. As evidence was solely non-comparative it is not possible to determine the accuracy of this interpretation.

Table 13: Summary of spirometry interpretation (LungHealth)

Study; Location	Key findings
Angus (2012); UK	19.1% (45 of 236) did not have obstruction: • 30 had normal function • 15 had restrictive function
Angus (2019) [Abstract]; UK	24.4% (181 of 741) deemed not to have obstructive spirometry pattern
Chakrabarti (2025a); UK	7.7% (404 of 5,221) had restrictive lung function
Chakrabarti (2025d) [Poster]; UK	Of 103 patients; • >50 had normal spirometry; • >40 had obstructive spirometry; • <10 patients had restrictive spirometry; • <5 patients showed a reversible pattern indicative of asthma.

Quality of spirometry performance

No studies were identified that reported this outcome.

Access to spirometry and the number of tests performed

The EAG note that LungHealth is a software only technology that relies on existing spirometers and their measurements when used in primary and community care settings. Despite this, the EAG consider it plausible that the spirometry test capacity could be increased through release of resources associated with reduction in staff interpretation time when implementing the technology. Unfortunately, no comparative evidence was available to determine whether implementation of LungHealth could increase access or the number of tests performed.

Time to perform and interpret spirometry

Angus et al. (2012) reported that patients were given a 45-minute appointment time to allow 15 minutes to perform spirometry and conduct a clinical examination; the EAG assumes that the remaining 30 minutes were apportioned to conduct the LungHealth computer-guided consultation and provide management recommendations. Authors did not report the time for a clinical review without the use of LungHealth, therefore it is difficult to put these results into context.

Time-to-diagnosis

No studies were identified that reported this outcome.

Number of referrals to secondary care for a diagnosis

No studies were identified that reported this outcome.

Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment

No studies were identified that reported this outcome.

Mortality

No studies were identified that reported this outcome.

Morbidity

No studies were identified that reported this outcome.

Clinician confidence in interpreting spirometry results and making diagnosis

No studies were identified that reported this outcome.

Clinician acceptability, ease of use, experience and satisfaction

One study (Angus et al. 2012) reported on feedback (measured via a Likert scale) from 7 nurses without previous specialty respiratory training after using LungHealth software following a 2-day mentoring period, Table 14. The EAG note that during this mentoring period that the staff had additional support from a trained respiratory nurse. Therefore, the generalisability of these results may not be reflective of how the technology would be used in NHS.

Table 14: Summary of clinician feedback (LungHealth)

Study; Location	Study design	Key findings
Angus (2012); UK	Service evaluation (n=7 nurses without previous specialty respiratory training)	• 6 out of 7 agreed that the use of software will help standardise patient care (1 tended to agree); • 5 out of 7 agreed that the flow ensures no aspect of assessment is omitted (2 tended to agree); • 4 out of 7 agreed that using the software would aid accurate diagnosis (3 tended to agree); • All agreed that they would need the following training to use the software selecting 1-2 days (options not reported).

Health-related quality of life

No studies were identified that reported this outcome.

Patient acceptability, ease of use, experience and satisfaction

No studies were identified that reported this outcome.

5.2.5 MIR Spiro (Medical International Research, MIR)

No evidence was identified specifically for MIR Spiro nor was any evidence provided by the company. In line with the inclusion criteria outlined in the EAG Protocol (2025) and Section 4.2 Included and excluded studies, the EAG

considered evidence for MIR spirometers. Three studies were identified using a MIR spirometer (Lusuardi et al. 2006, MIR Spirobank Office; Khatoon et al. 2025, MIR Spirobank Smart; Castro et al. 2024, MIR Spirobank II). The only comparative evidence available is an Italian RCT, which reported on the diagnostic accuracy of the spirometer in a primary care setting compared with secondary care pulmonary specialist expert diagnosis, although the EAG note that the software used is unlikely to be reflective of the contemporary model in scope and the impact of the software on informing the diagnosis was not reported. The remaining two non-comparative studies were set in the UK (Khatoon et al. 2025) and the US (Castro et al. 2024), which both captured evidence relating to patient experience only.

Diagnostic accuracy of initial diagnosis

The Italian RCT by Lusuardi et al. (2006) compared primary care diagnosis with and without the use of the MIR Spirobank Office spirometer (the EAG assume this is a predecessor to the currently available MIR Spirobank II spirometers), Table 15. The authors noted that the spirometer "has a quality check for reliability and reproducibility of spirometric curves (according to ATS criteria), allowing to accept or refuse a test, and provided an automated interpretation of spirometry". No further information on this interpretation was provided however, the EAG note that, given the date of publication, this may not be representative of the technology's current algorithmic function and capability of more recent iterations of the technology and the impact of the algorithms specifically in supporting diagnosis is unclear. Of the 333 patients enrolled, 149 were considered random protocol violators (notably, a higher proportion of patients had conventional evaluation plus spirometry) and 44 patients did not receive a GP diagnosis (missing diagnosis). Statistical analysis was therefore applied to different case series (all patients, all patients except those with missing diagnosis, only non-random violators, only non-random violators except those with a missing diagnosis). For all case series, the level of agreement between GPs and specialists was not found to be statistically different regardless of whether spirometry was performed.

Table 15: Summary of diagnostic concordance (MIR Spirobank Office)

Study; Location	Reference standard	Intervention	Diagnostic concordance (per-protocol)	Diagnostic concordance (intention-to-treat protocol)
Lusuardi (2006); Italy	Pulmonary specialists (n=NR); secondary care, blinded	GP diagnosis with MIR Spirobank Office spirometry	78.6%	57.9%

Abbreviations: NR, not reported

Accuracy of interpretation of spirometry

No comparative evidence was available to determine the accuracy of the spirometry pattern interpretation. Lusuardi et al. (2006) reported the proportion of spirometry pattern results (number of patients not reported): findings in the normal range were 61.8%; 16.4% had an obstructive pattern, 12.0% had a mixed pattern, and 9.8% had a low FVC without obstruction, Table 16.

Table 16: Summary of spirometry interpretation (MIR Spiro)

Study; Location	Study design (number of patients)	Key findings
Lusuardi (2006); Italy	RCT (n=NR)	• 61.8% normal results • 16.4% obstructive function • 12.0% mixed pattern • 9.8% low FVC without obstruction

Abbreviations: FVC, forced vital capacity; NR, not reported; RCT, randomised controlled trial

Quality of spirometry performance

No studies were identified that reported this outcome.

Access to spirometry and the number of tests performed

No studies were identified that reported this outcome.

Time to perform and interpret spirometry

No comparative evidence was available for the time taken to perform spirometry, however Lusuardi et al. (2006) reported that the mean time (SD) required to instruct patients for spirometry was 5.6 (3.1) minutes and mean spirometry performance time using the MIR Spirobank II was 6.4 (3.5)

minutes. The EAG note that this RCT also included a parallel observational study, which included additional patients with a known diagnosis of COPD or asthma, therefore the EAG assume that this time may not be representative of an exclusively undiagnosed or spirometry-naive population.

Time-to-diagnosis

No studies were identified that reported this outcome.

Number of referrals to secondary care for a diagnosis

No studies were identified that reported this outcome.

Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment

No studies were identified that reported this outcome.

Mortality

No studies were identified that reported this outcome.

Morbidity

No studies were identified that reported this outcome.

Clinician confidence in interpreting spirometry results and making diagnosis

No studies were identified that reported this outcome.

Clinician acceptability, ease of use, experience and satisfaction

Lusuardi et al. (2006) reported feedback from GPs (n=NR) about the usefulness of the MIR Spirobank Office spirometer for use in primary care to support clinical diagnosis of lung conditions (including asthma and COPD) at the end of the study, Table 17. Authors noted that the enrolment trend also dropped significantly towards the end of the study, suggesting that the usefulness of the test may have supported a steady application of the test throughout the study period.

Table 17: Summary of clinician feedback (MIR Spirobank Office)

Study; Location	Study design	Key findings
Lusuardi (2006); Italy	RCT (n=104 GPs) plus parallel observational (n=236 GPs, final number completing questionnaire NR)	Clinician feedback on usefulness of MIR Spirobank Office spirometer (at end of 9-month trial period): • very useful: 57.1% • moderately useful: 15.0% • useless: 0.3% • did not respond: 27.6% Study enrolment trend: • 74% patients recruited in first 5 months • Sharp decrease in enrolment in month 6 with steady reduction to 16 patients (0.8%) in the final month

Abbreviations: NR, not reported; RCT, randomised controlled trial

Health-related quality of life

No studies were identified that reported this outcome.

Patient acceptability, ease of use, experience and satisfaction

Two studies reported on patient acceptability, Table 18. Khatoon et al. (2025) reported a qualitative study within the Rapid Asthma Diagnostic Clinic for Asthma study (RADicA), identifying patient views on home spirometry testing in a subset of 15 patients undergoing home daily testing. Patients were asked to perform 2 to 4 daily spirometry measurements using the MIR Spirobank Smart, which connected to an app to provide a virtual assistant for optimum technique and patients were provided with a simple guide for what the results may mean. It is unclear whether these guides were based on the software providing reactive interpretation or whether these were independent guides issued to patients by the study team. The US observational cohort study by Castro et al. (2024) reported on the usability of the MIR Spirobank II spirometer for home monitoring of severe uncontrolled asthma (either exacerbation requiring 2 or more oral corticosteroid bursts – assumed to mean a short-term course of oral corticosteroids - or 1 or more A&E visits or hospitalisations in the 2 years prior to enrolment, or an Asthma Control Questionnaire score greater than 1.5, or Asthma Control Test score less than 20 at baseline, and currently using a SABA as rescue medication). Patients aged 12 years and older were asked whether it was easy to take the

spirometry test using the technology in weeks 4 and 20 of the 24-week study period using a 7-point Likert scale.

Table 18: Summary of patient feedback (MIR Spirobank)

Study; Location	Study design	Key findings
Khatoon (2025) RADicA study [ISRCTN11676160]; UK	Qualitative study (n=15 patients undergoing home testing; 2 to 4 daily spirometry measurements)	• For most participants (not quantified), there was a recognition that home testing could support the accurate diagnosis of asthma in addition to enable people with asthma to better self-manage their condition. • Some participants noted that the responsibility of performing testing without clinical oversight was overwhelming and perceived some tasks as unnecessary or overly complicated. • Participants noted that the MIR Spirobank Smart was portable, and the app was easy to use however the number of attempts taken to get accurate tests could be burdensome and the app had technical issues. • Participants reported that the icons on the spirometry app could be simplified and include a clear explanation of their meaning.
Castro (2024); US	Observational cohort (n=45 patients at week 4, n=39 at week 20)	Reduction in usability during study period (measured using 7-point Likert scale*) from 5.3 (week 4) to 4.8 (week 20).

Key: *7-point Likert scale used (1=strongly disagree, 7=strongly agree)

5.2.6 NuvoAir (NuvoAir)

Six studies were available for NuvoAir, including two submitted in confidence by the company to the EAG. [redacted] Evidence captured spirometry access, accuracy, quality and qualitative outcomes (clinician and patient acceptability) in children and young people with suspected asthma.

Diagnostic accuracy of initial diagnosis

Four studies reported on accuracy of the initial asthma diagnosis, Table 19, however comparative evidence that reported the accuracy of the algorithm interpretation against standard care was unavailable, which means it has not been possible to determine the sensitivity and specificity of using NuvoAir to inform a diagnosis, nor determine the accuracy of the algorithm interpretation against standard care.

All studies provide limited data and with testing conducted at home over a period up to 12 weeks, which may limit generalisation to the decision problem of a single test in primary care or the CDC setting. Furthermore, [redacted]. Parrott et al. (2023) noted that 67% patients received an accurate diagnosis at the end of a 12-week Asthma Home Programme, however no further details were given. Robshaw et al. (2024) reported that 38% of 112 adults with asthma had diagnosis confirmation and 5 patients had their diagnosis changed and 26% required an onward referral, including to support final diagnosis.

Table 19: Summary of diagnostic accuracy of initial diagnosis (NuvoAir)

Study; Location	Population (setting) [period of home testing]	Key findings
Tuli 2025 [AiC]; [redacted]	[redacted]	[redacted]

Study; Location	Population (setting) [period of home testing]	Key findings
	[redacted]	[redacted]
Gray 2026 [AiC]; [redacted]	[redacted]	[redacted]
Parrott (2023) [Abstract]; UK	n=40 adults (12-week Asthma Home Programme, following referral for either uncertain diagnosis of asthma or assessment of uncontrolled symptoms) [1 to 4 tests per week supported virtually by NuvoAir physiologists over 12 weeks]	67% received an accurate diagnosis; no additional information was provided.
Robshaw (2024) [Abstract]; UK	n=112 adults referred to NuvoAir because of uncontrolled asthma with uncertain cause, asthma uncertain with no evidence of obstruction or uncontrolled asthma with adherence concerns [4 tests per week for up to 12 weeks]	• 38% patients had diagnosis confirmation (including 14 patients with confirmed asthma), and 5 where the asthma diagnosis was changed and the patient referred back to their GP. • A further 28% had medication optimisation, 26% had an onward referral and 8% did not engage or withdrew from assessment.

Abbreviations: AUC, area under the curve; EAG, External Assessment Group; FeNO, fractional exhaled nitric oxide; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity

Accuracy of interpretation of spirometry

No studies were identified that reported this outcome.

Quality of spirometry performance

Four studies reported on the quality of spirometry, Table 20. No comparative evidence was identified that reported the accuracy of the algorithm quality assessment against standard care.

Kocks et al. (2023) reported outcomes for 140 patients with an asthma- or COPD-related clinic-based spirometry indication in the Netherlands or Sweden. Patients were given a home-based spirometer (assumed to be NuvoAir as evidence submitted by the Company), of which 89.3% completed a home spirometry session. Reasons for non-completion or unacceptable tests not reported. Authors also noted that there was a small mean difference in spirometry results observed at home versus in clinic with FEV1 and FVC being 0.076 L and 0.094 L higher at home respectively

Table 20: Summary of the quality of spirometry performance (NuvoAir)

Study; Location	Population; [period of home testing]	Number of patients (number of tests)	Proportion of patients with at least one acceptable spirometry measurement	Proportion of tests graded acceptable (grading criteria used)
Gray (2026) [AiC]; [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Study; Location	Population; [period of home testing]	Number of patients (number of tests)	Proportion of patients with at least one acceptable spirometry measurement	Proportion of tests graded acceptable (grading criteria used)
Kocks (2023) [Pre-print]; Netherlands, Sweden	Adults with asthma or COPD [NR]	140 (NR), - Asthma (n=50) - COPD (n=9) - Asthma and COPD (n=7) - No asthma or COPD diagnosis (n=32) - Unknown condition (n=27) - No valid tests (n=15)	125/140 (89.3%)	59.2% (at least 2 acceptable measurements meeting ATS/ERS 2019 guidelines)
Parrott (2023) [Abstract]; UK	Adults with confirmed or suspected asthma [1 to 4 times per week spirometry tests supported virtually by NuvoAir physiologists over 12 weeks]	40 (NR)	NR	77% (Grade A to C, using ATS/ERS 2005 guidelines)
Robshaw (2024) [Abstract]; UK	Adults with confirmed or suspected asthma [4 tests per week for up to 12 weeks]	112 (NR)	NR	78% (NR)
Tuli (2025) [AiC]; [redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Abbreviations: ATS, American Thoracic Society; COPD, chronic obstructive pulmonary disease; ERS, European Respiratory Society; FeNO, fractional exhaled nitric oxide; NR, not reported

Access to spirometry and the number of tests performed

The EAG acknowledges that the use of NuvoAir within the diagnostic pathway may offer an increase in capacity of testing within a primary care setting (such as, where patients can be referred to NuvoAir for diagnostic spirometry in areas where local spirometry access is not available) in addition to having multiple tests performed for the same individual over a fixed time period to support diagnosis. The EAG also acknowledges that the number of tests performed will be influenced by the quality of the test, such as the number of tests repeated when sufficient quality is not met. The EAG did not identify any comparative evidence reporting the differences in testing capacity from the introduction of NuvoAir, however five studies reported the quality and quantity of tests performed during a NuvoAir diagnostic pathway, Table 20.

Time to perform and interpret spirometry

No studies were identified that reported this outcome.

Time-to-diagnosis

No studies were identified that reported this outcome.

Number of referrals to secondary care for diagnosis

Two studies (both in a population with suspected or diagnosed asthma) reported the proportion of referrals to secondary care for diagnosis, range between 22% and 26%,

Table 21. The UK service evaluation by Robshaw et al. (2024) reported reasons for an onward referral were awaiting inducible laryngeal obstruction (n=2) or biologic (n=5) assessment, requirement for further investigations (n=16) or haematology referral (n=1), concurrent diagnosis was suspected (n=28), or GP medication review was required (n=1). The EAG assumes that multiple reasons for onward referral could apply. Parrott et al. (2023) reported that 22% of 40 patients using the NuvoAir 12-week Asthma Home Programme had an onward referral for an alternative diagnosis, however no further details were provided and it is unclear whether these referrals were managed within primary or secondary care.

The abstract shared in confidence by the Company (Gray et al. 2026) reported [redacted]

Table 21: Summary of referrals for diagnosis (NuvoAir)

Study; Location	Period of home-spirometry testing	Proportion with onward referral for diagnosis, %
Parrott (2023) [Abstract]; UK	12 weeks	22.0 (9/40)
Robshaw (2024) [Abstract]; UK	4 times per week; up to 12 weeks	26.0 (NR/112)

Abbreviations: NR, not reported

Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment

No studies were identified that reported this outcome.

Mortality

No studies were identified that reported this outcome.

Morbidity

No studies were identified that reported this outcome.

Clinician confidence in interpreting spirometry results and making diagnosis

Kocks et al. (2023) used questionnaires to gain feedback from 24 practice nurses and 4 GPs, of which only 7% agreed that the use of home spirometry improved the diagnostic process and 4% felt that it provided better distinction between asthma and COPD, Table 22.

Table 22: Summary of clinician confidence (NuvoAir)

Study; Location	Study design	Key findings
Kocks (2023) [Pre-print]; Netherlands, Sweden	Cross-sectional cohort, mixed methods (n=24 practice nurses, 4 GPs)	NuvoAir improved diagnostic process: 7% (2/28) NuvoAir provided better distinction between asthma and COPD: 4% (1/28)

Abbreviations: COPD, chronic obstructive pulmonary disease;

Clinician acceptability, ease of use, experience and satisfaction

Kocks et al. (2023) used questionnaires to gain feedback from 24 practice nurses and 4 GPs, of which, 82% agreed that home spirometry was possible, executable (78%) and implementable (68%). However, only 50% agreed that NuvoAir was easy to use although it is unclear whether this relates to ease of use experienced by patients or aspects of the technology being used by the clinician, such as viewing reports or engaging with the NuvoAir physiologists, Table 23.

Table 23: Summary of clinician feedback (NuvoAir)

Study; Location	Study design	Key findings
Kocks (2023) [Pre-print]; Netherlands, Sweden	Cross-sectional cohort, mixed methods (n=24 practice nurses, 4 GPs)	NuvoAir home spirometry possible: 82% (23/28) NuvoAir home spirometry executable: 78% (22/28) NuvoAir home spirometry implementable: 68% (19/28) NuvoAir easy to use: 50% (14/28)

Patient acceptability, ease of use, experience and satisfaction

Three studies reported on patient acceptability of NuvoAir, Table 24. Two studies (including the abstract provided academic-in-confidence by the company) [redacted]

Table 24: Summary of patient feedback (NuvoAir)

Study; Location	User perspective	Key findings
Coughlin (2021) [Abstract]; UK	Parents and carers of paediatric patients (n=18)	NuvoAir easy to set up: 82.4% (NR/18) Easy to perform NuvoAir spirometry: 81.3% (NR/18)

Study; Location	User perspective	Key findings
Gray (2026) [AiC]; [redacted]	[redacted]	[redacted]
Kocks (2023) [Abstract]; Netherlands, Sweden	Adults with asthma or COPD (n=101); unclear if this population was exclusively in a spirometry-naive population	NuvoAir app instructions unclear: 10% (10/101) Experienced problems with NuvoAir app: 17% (17/101) Felt safe performing NuvoAir home spirometry: 81% (81/101) Needed help from a professional to use NuvoAir: 24% (24/101)
Robshaw (2024) [Abstract]; UK	Adults with suspected or confirmed asthma (n=120)	8% did not engage or withdrew from assessment

Abbreviations: NR, not reported

5.3 Adverse events and clinical risk

The EAG searched MHRA Field Safety Notices from 01 January 2020 to 01 September 2025 and found no mention of any of the company or technology names listed in the Final Scope.

Home-based BDR testing with spirometry (NuvoAir)

The EAG note that bronchodilator reversibility (BDR) testing with spirometry is recommended to differentiate diagnosis of asthma from COPD and is recommended as a diagnostic test for both conditions, Table 1, NICE Final Scope (2025). NuvoAir confirmed that it is possible to perform "home-based informal bronchodilator assessment in instances where the patient already has inhalers prescribed". However, also stated that where patients do not already have an inhaler, responsibilities for prescribing of inhaler lies with the referring clinician and NuvoAir provide direction to the patient on how to administer themselves for the purpose of the bronchodilator assessment in line with their prescription and inhaler type. Adverse events to spirometry, with or without the use of bronchodilators, are raised immediately with the patient's referrer (notification mechanism not detailed), and the NuvoAir physiologist supporting the assessment will monitor the individual's recovery through contact with the patient and referrer. No further detail was provided. Two

Experts advised that it would be unlikely or unfeasible to perform diagnostic spirometry with BDR testing at home due to the technical standard and inhaler technique required, which may impact the quality of the test, however one noted that inhaler bronchodilators are safe for most patients to use (Appendix D3).

5.4 Clinical evidence summary and interpretation

The main aim of this assessment was to determine the evidence available for the technologies in scope and identify evidence gaps to support future evidence generation. In line with the EVA process and methods, the EAG conducted a rapid review and identified 30 sources of evidence within this assessment. The evidence included abstracts, posters, editorials, pre-print publications and information provided in confidence, which may lack peer-review.

The key value propositions of these technologies are the potential benefits for improvements in the accuracy of spirometry quality and interpretation when used in a primary care setting to inform initial diagnosis of lung conditions. This extends to the accuracy of initial diagnosis when used for a clinical review in people who have an existing diagnosis of a lung condition. These value propositions aim to ensure that people with lung conditions are diagnosed accurately and receive appropriate management, which has implications for patient wellbeing and NHS resources.

Implementation of the technologies to support diagnosis may also increase access to or reduce waiting time for spirometry through release of resources to increase testing capacity (driven by a reduction in interpretation or testing time) or by offering an independent home-based diagnostic pathway (NuvoAir).

Summary of evidence

The evidence base for the included technologies was varied. The most comprehensive evidence was for ArtiQ.Spiro, in terms of quality,

generalisability to a UK NHS setting and for populations and outcomes in scope. Evidence for LungHealth and NuvoAir consists mostly of real-world evidence from a UK NHS setting, but this was largely non-comparative and in a diagnosed (asthma or COPD) population, therefore may lack generalisability to the application in a primary care diagnostic setting. The EAG also note that in some studies NuvoAir included mixed populations of spirometry naive and non-naive patients, which may affect the proportion of those who are able to provide valid spirometry at home. There is a lack of evidence in scope for EasyOne Connect and evidence was limited for MIR Spiro or GoSpiro. There was limited evidence in patients with suspected ILD or restrictive lung conditions.

Overall, patient feedback was generally positive for the use of decision support software being used with spirometry interpretation and diagnosis in primary care. Where relevant, spirometers were generally reported by patients to be easy to use at home. Concerns related to whether there was sufficient clinical oversight and that final decision-making should remain with the healthcare professionals. Clinicians noted some benefits to the introduction of the technologies, including improved confidence with decision-making and release of clinical time, however differences between those making diagnoses with and without the use of the technologies were not always significantly different, nor were algorithm-supported pathways preferred.

Comparative evidence for the impact of the technologies on waiting time (such as time-to-diagnosis or time to perform and interpret spirometry) was limited across all technologies. Long-term outcomes were not reported or very limited, such as number of hospital admissions or treatment because of missed or incorrect diagnoses, mortality, morbidity, health-related quality of life. This impacts consideration of the long-term clinical- or cost-effectiveness of the introduction of these technologies. These outcomes may be more greatly influenced by differences in implementation, therefore may not be generalisable across technologies.

6. Economic evidence

6.1 Existing economic evidence

Initial assessment of the clinical results suggested that they would not provide much economic evidence. Economic evaluation literature searches were developed by an information specialist to include additional search terms that described the product functional specifications, these were searched as free-text, keyword, and controlled vocabulary terms.

Structurally, the subject requirements of the searches (where platform search functionality permitted) were lung diseases and two out of three of: diagnosis, spirometry and algorithm-related terms. The final search strategy was developed in Embase (OVID) and then translated, adapted and run on 01 September 2025 independently for each individual database (Ovid Medline, RePEc IDEAS, PEDE, NHS EED, INAHTA CEA Registry). An expanded version of the Canadian Agency for Drugs and Technologies in Health narrow economic search filter (CADTH, 2021) was appended to the Medline and Embase searches in order to identify cost and economic studies in databases that are not specific to health economics (Appendix A1).

An additional search was conducted to identify economic modelling papers describing the diagnostic pathway for asthma, COPD or restrictive lung diseases to support the development of a conceptual economic model. A total of 396 records were identified; 315 remained after deduplication. To capture evidence most relevant to the decision problem the EAG applied a date restriction of 2019 (noting that NG115 “Chronic obstructive pulmonary disease in over 16s: diagnosis and management” had an evidence review published in 2019, and NG245 “Asthma: diagnosis, monitoring and chronic asthma management” had an evidence review in 2024). After this date restriction was applied, 112 titles and abstracts remained. A single reviewer (KK), with a 10% sample checked by a second reviewer (RP), sifted through the titles and abstracts and found none were specific to the technologies listed in the scope. Full papers retrieved were checked for inclusion by two reviewers (KK, RP).

To retrieve results describing methods in sufficient detail, the EAG restricted included evidence to full papers.

From the economic search (including reference trawling of identified reviews), 11 papers were considered partly relevant to inform development of a conceptual economic model (PRISMA diagram: economic evidence – Appendix A3), which was then used to determine key drivers and areas of uncertainty. This included 4 papers in people with asthma, 5 in people with COPD and 2 in people with restrictive lung disease (summarised in Appendix B1).

Three companies also provided specific economic evidence related to the technologies listed in the scope:

- ArtiQ.Spiro: 2 abstracts (1 was already considered within clinical evidence [Hayes et al. 2025b], and 1 was provided academic-in-confidence) where the patient population were not defined;
- LungHealth: 2 conference abstracts where the device was not explicitly named and 1 bespoke cost calculator output not in the public domain, in a population with COPD;
- NuvoAir: 1 executable economic model developed in Microsoft Excel with accompanying report not in the public domain, in a population with asthma.

Economic evidence submitted by 3 companies is summarised in Table 25. No economic evidence was submitted by the remaining 3 companies, and no economic evidence was identified specific to a population with restrictive lung disease.

Table 25: Summary of economic evidence submitted by companies

#	Study (year); Country	Population [details]	Study description	Key results	EAG comment
1.	**ArtiQ.Spiro** [AiC] [redacted]	[redacted]	[redacted]	[redacted]	[redacted]
2.	Davies (Am J Resp Crit Care Med, 2012; A3731) [Abstract] UK	COPD [Confirmed diagnosis from COPD databases from 16 practices]	Service evaluation (economic prediction); price year not reported. **LungHealth** (device not explicitly mentioned; abstract highlighted by Company and company-affiliated co-authors).	Of 293 patients with a diagnosis of COPD, 236 had spirometry available, 45 (19%) of which determined not to have COPD. Removing planned COPD follow-up would save £21,000 per annum. Removing prescriptions (assuming 8 scripts per year) would save additional £210,000 per year. Of the remaining 191 patients with confirmed COPD, 169 had recommended altered prescribing of inhalers or dose/device. Switching 17% of patients on high dose prescriptions of inhaled corticosteroids/LABA combination to dry powder devices would save £313,000 per year. Adding ICS/LABA combination in 16% of patients with severe or very severe disease would increase drug costs but would also reduce admissions and would result in overall cost reduction of £100,000 per annum. Of the 55 current smokers, 47% were referred for smoking cessation support.	Clinical outcomes included in Angus et al. 2012, included in clinical evidence. Only available in abstract, therefore limitation detail in methods and results. Single-arm empirical data, and costs stated are projections. The extent projections could be realised in practice is not known, not all projected savings would result in financial savings as some e.g. reduction in admissions would free capacity for other uses.
3.	Thompson (Am J Respir Crit Care Med, 2013c; A4379) [Abstract] UK	COPD [Confirmed diagnosis from COPD databases from 13 practices]	Service evaluation (economic evaluation); price year not reported. **LungHealth** (device not explicitly mentioned; abstract highlighted by Company and company-affiliated co-authors).	Of 417 patients on COPD registers, 338 had spirometry confirmed COPD, the 79 patients remaining did not have obstructive spirometry. Authors state use of computer-guided consultation may double initial time (undefined), with additional cost of software of £149,000. However, removing annual reviews for the 79 cases where COPD was not confirmed would save £23,000 in appointments, and £226,000 of inhaled medications although the time period was not stated. Seven of 11 cases of severe or very severe COPD had ICS/LABA combination added, 7 of 95 cases with greater FEV1 (no further detail provided). 27 of 226 already on ICS/LABA combination were changed from MDI to DPI, with cost saving of £115,000 per annum (assuming 8 scripts per year). Seventeen of 165 not on LAMA had it added. No patients were referred for oxygen assessments without hypoxia. Only 7.5% of those eligible were referred for pulmonary rehabilitation. Total cost savings of £7,000 when reduction in admissions were balanced against programme costs were reported; although the time period was not stated.	Clinical outcomes also included in Thompson 2013b, included in clinical evidence. Only available in abstract, therefore limitation detail in methods and results. Single-arm empirical data, and costs stated are projections. The extent projections could be realised in practice is not known, not all projected savings would result in financial savings as some e.g. reduction in outpatient appointments would free capacity for other uses.
4.	Bespoke cost calculator output (unpublished); UK	COPD	Estimated misdiagnoses when implementing **LungHealth** (device not explicitly mentioned; however, submitted by Company). Price year not reported.	Practice population of 8,640: 164 patients with COPD, with 33 estimated misdiagnoses. • Estimated savings from stopped medication: £5,613 by practice, £214,389 across CCG. [based on real-life experience in CCG of 50 consecutive patients in Oct 2019 misdiagnosed with COPD]. • Estimated savings from no longer requiring annual COPD review: £1,263 by practice, £48,270 across CCG • Cost savings associated with successful pulmonary rehabilitation referral and completion reported as cost neural. [Note that this output also reports that there is no publicly available data to quantify savings or improvements in quality of life]. • Cost saving through medicines optimisation: £170.72 [Based on 100 consecutive cases with moderate, severe or very severe COPD (defined as GOLD status 2, 3 or 4) seen post-Oct 2019].	Model was created and validated by Prof Pearson (former Professor of Clinical Evaluation at Liverpool University Hospital NHS FT, and Director of LungHealth). Assumes all patients with COPD currently obtain an annual review (90% by nurse, 10% by GP). Company state that following consultation patient may have diagnosis of COPD removed, but diagnosis of asthma confirmed (therefore continued or commencement of inhaled steroid therapy). Single-arm empirical data, costs stated are projections based on real-life estimates. The extent projections could be realised in practice is not known, not all projected savings would result in

#	Study (year); Country	Population [details]	Study description	Key results	EAG comment
				• Overall saving of £9,546 for practice, £279,610 for the CCG.	financial savings to the health service as some e.g. reduction in admissions would free capacity for other uses.
5.	Executable economic model, Microsoft Excel (June 2023); UK	Asthma [43,000 adult patients with uncontrolled asthma]	Variants of model included due to different places in pathway where the technology can be deployed (primary, secondary and tertiary care). Due to relevance to the decision problem the EAG focused its review on the economic model when **NuvoAir** was implemented in a primary care setting. Model includes costs of ambulance transport, treatment (including biologics) and other investigations conducted, as well as a unit cost for NuvoAir (£300, which the company confirmed was a prior cost for a 3-month asthma assessment which has been replaced with a 2-week disease agnostic assessment), which is assumed to be a per-patient cost. Price year not reported; assumed 2023. Assumed that patients with controlled asthma do not have exacerbations, controlled asthma patients consume 2 canisters of SABA a year, uncontrolled average 6 canisters per year.	Model assumes: • Less GP appointments with practice nurse (2.34 annually with standard care, 1.43 with NuvoAir) • 56.4% have peak flow, 30.50% spirometry and 3.89% bronchial reversibility testing in primary care standard care, however that these are replaced (set to 0%) in the NuvoAir arm. • The EAG noted differences in the percentage of patients receiving oral steroids (prednisone) in primary care, proportion of poor adherence is identified and successful attempts made to address it, proportion of poor technique is identified, and successful attempts are made to address it. • Treatment benefits applied were the same in both arms. • Difference in percentage of patients who receive support and gain asthma control in primary care between arms (34.79% in standard care, 39.28% with NuvoAir). • Duration spent under primary care was different between arms (30 months standard care, 3 in NuvoAir). • Proportion of patients referred to secondary care when required in one year was different between arms (26% in standard care, 53% in NuvoAir) The reports stated a cost saving of £72 per patient where NuvoAir is provided (EAG unable to verify this figure using the executable model provided). Stated that 5,032 extra patients gain asthma control due to NuvoAir in year 1, with 7,179 in year 2, and 5,502 in year 3 (the EAG was unable to verify these numbers).	Independent health economics assessment of its asthma service by Mind over Matter Medtech via the European Regional Development Fund's Cheshire and Warrington Health Matters programme.

Abbreviations: CCG, clinical commissioning group; COPD, chronic obstructive pulmonary disease; DPI, dry powder inhaler; EAG, external assessment group; EAG, External Assessment Group; FEV1, forced expiratory volume in 1 second; GOLD, Global Initiative for Chronic Obstructive Lung Disease; ICS, inhaled corticosteroids; LABA, long-acting beta-2 agonist; MDI, metered dose inhaler; LAMA, long-acting muscarinic antagonist; QALY, quality-adjusted life year; RCT, randomised control trial; SABA, short-acting beta-2 agonist

6.1.1 Relevant economic models from NICE guidelines

The EAG also reviewed NICE clinical guidelines for relevant economic models. This included the economic analysis used to support the update of BTS/NICE/SIGN collaborative guideline NG245 on diagnosis, monitoring and chronic asthma management (NG245, 2024). This included a diagnostic accuracy decision tree model that compared testing strategies for diagnosing asthma, where the populations then entered a Markov model to simulate treatment and management. The EAG also considered the economic analysis that supported NG115 on diagnosis and management of chronic obstructive pulmonary disease in over 16s (NG115, 2019), which incorporated a Markov model to determine impact of different management strategies.

6.2 Conceptual economic model

To cover the breadth of the populations included in the Final Scope and different value propositions between technologies, the EAG developed a conceptual economic model. The model was based on methods and assumptions from published economic resources (NG245, NG115) to demonstrate key drivers and areas of uncertainty if the technologies were used in the current NHS pathway. The aim of the conceptual economic model was to inform future data collection efforts. The model lacked full parameterisation and as such the results should not be interpreted as evidence or lack of evidence of cost-effectiveness. Instead, the economic model provided a framework that could be used to highlight evidence gaps and key drivers associated with technologies used to support spirometry interpretation in the diagnostic pathway of lung diseases when compared with standard care, which should be addressed prior to an economic evaluation in future.

The model itself was coded in R Programming Language, using the *'rdecision'* package. The model reads in an input table (Microsoft Excel); where each column represents a parameter, and each row represents a new scenario modelled. The EAG also developed an application using the 'Shiny' package

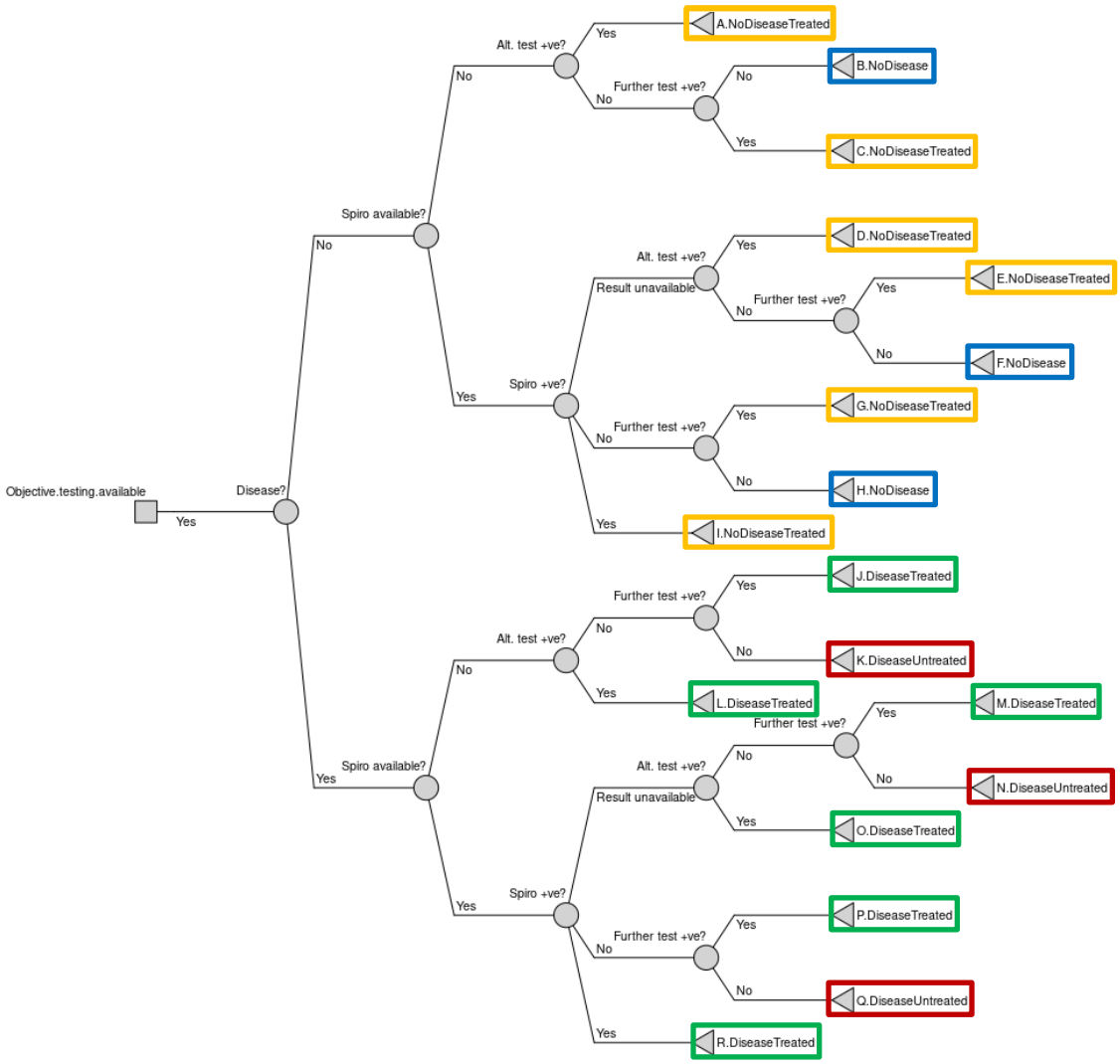
around the economic model to make the model more accessible and enable stakeholders to see the impact of changes to input parameters. The model was developed from a UK NHS and Personal Social Services (PSS) perspective, over a 10-year time horizon with monthly cycles. The EAG note that the cycle length was chosen to reflect NHS practice regarding the diagnostic testing phase (where Experts advised 1 month was appropriate to evaluate impact of prescribed medication; Appendix D2). Alternative time horizons were considered in sensitivity analysis. A discounting rate of 3.5% for costs and utilities was applied in line with the NICE reference case (NICE PMG9, 2013). The EAG note that the management element of the economic model for NG245 (2024) used a 5-year time horizon and it noted that there was limited data around referrals after severe exacerbation, and that switching treatment would limit long-term modelling. The EAG considered the longer time horizon appropriate due to the focus being on diagnosis of lung conditions and with a potentially low difference in cost between the intervention and comparator, the longer time horizon allows the long-term impact of this difference, and of the relatively small difference in QALYs, to be more fully explored.

The starting population included 1,000 patients suspected to have asthma or COPD who had attended their GP for testing and were eligible for spirometry. The EAG assumed that at the start of the model any prior testing for the disease had had a negative result, leading to needing an objective test, such as spirometry. It is important to note that the starting population was assumed to be those suspected of having the disease, based on their clinical history and symptoms, including those who have the disease and are as yet undiagnosed. The EAG has assumed a prevalence of the disease based on this, for which the diagnostic accuracy of the technologies will be used to categorise the population into true positives, true negatives, false positives, and false negatives.

6.2.1 Model structure

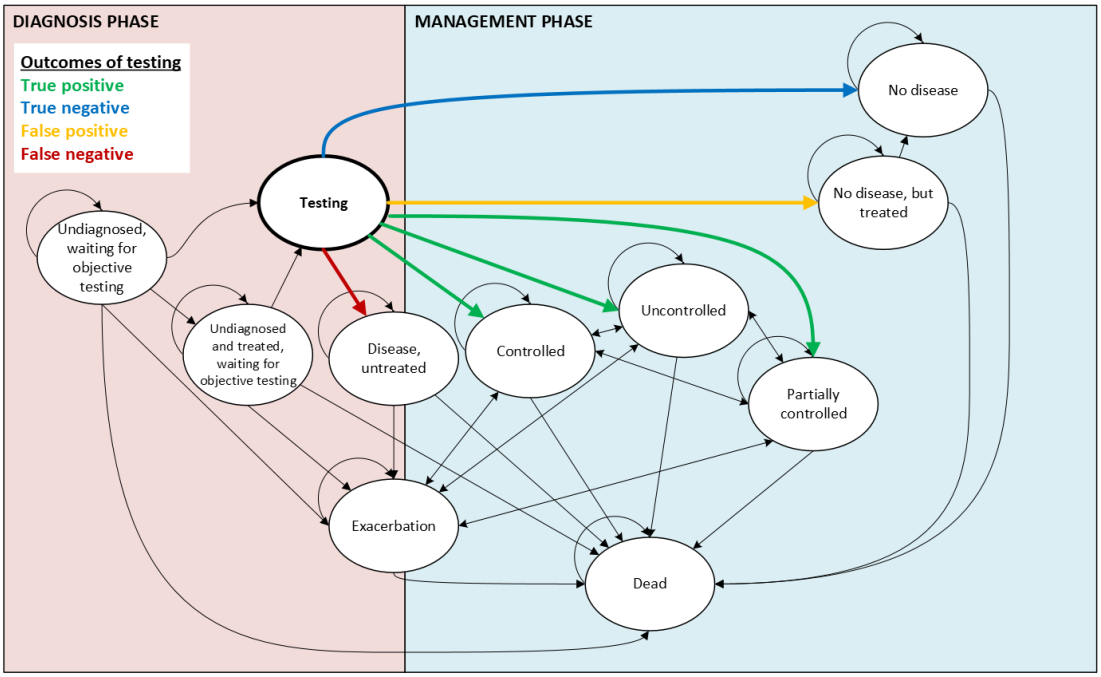
The EAG developed a conceptual economic model where the general structure could apply to all asthma, COPD and restrictive lung disease populations in scope. The structure incorporated a decision tree (Figure 2) to model the diagnostic testing pathway, which is embedded within a “Testing” state of a Markov model (Figure 3), used to model the wider care pathway of diagnosis and management. This approach also enabled the EAG to consider two value propositions of the included technologies that were raised at the scoping workshop with Experts and companies present: 1) improved diagnostic accuracy, and 2) reduced waiting times. The latter is supported by the recent survey by Asthma + Lung UK (2025), which stated that only 8 of 32 responding Integrated Care Systems said that they had enough spirometry testing capacity to meet the demand of new referrals and to address backlog.

Figure 2: Conceptual economic model diagram (decision tree)



Key: Green=True positive, Blue=True negative, Yellow=False positive, Red=False negative

Figure 3: Conceptual economic model diagram (Markov model)



The Markov model is made up of 11 states:

- **Undiagnosed, waiting for objective testing:** the population being modelled would start in this state when the need for objective testing has been identified and they begin waiting to be tested.
- **Undiagnosed, treated, waiting for objective testing**: this state is populated from the previous **Undiagnosed** state at the rate at which patients would be placed on treatment while waiting for objective testing to be carried out. The rate of transition from these two states to **Testing** would be used to model waiting times.
- **Testing:** patients would transition to this state from the **Undiagnosed** states when objective testing is available. The population would stay in this testing state for one cycle only, while they move through the decision tree shown in Figure 2, and described subsequently.
- **Disease, untreated:** patients who receive a false negative diagnosis move into this state from the **Testing** state. Patients in this state have the highest exacerbation rate. Patients remain here until they experience an exacerbation or die.
- **Exacerbation:** patients may transition to this state from all other states in the model, except the **Dead** state, and **No disease** states.

This state accounts for an acute exacerbation of the lung condition, leading to treatment in primary care, A&E or as a hospital inpatient. Patients may transition from this state to **Dead**, or to the **Controlled**, **Partially controlled**, and **Uncontrolled** states.

- **No disease but treated:** patients in this state have been incorrectly diagnosed with the disease they were suspected of having (false positive) and are therefore receiving inappropriate treatment. The model will allow a proportion of these to transition to the **No disease** state, and otherwise, the only transition available from this state is to **Dead** (based on standardised mortality rate based on age and sex).
- **No disease:** patients in this state have been diagnosed as not having the disease they were suspected of having. A proportion of these patients will be true negatives who enter this state straight from the testing state, who will remain in this state until they transition to **Dead**. The remaining patients will have been incorrectly diagnosed and treated, and will enter the state from **No disease, but treated**.
- **Controlled:** patients in this state have controlled disease (that is they are diagnosed with disease, receive treatment, have minimal or no symptoms and lowest exacerbation rate). Patients in this state may transition to **Partially controlled**, **Uncontrolled**, **Exacerbation** or **Dead**.
- **Partially controlled:** patients in this state have partially controlled disease (that is they are diagnosed with disease, receive treatment have some symptoms and increased exacerbation rate), and may transition to **Controlled**, **Uncontrolled**, **Exacerbation** or **Dead**.
- **Uncontrolled:** patients in this state have uncontrolled disease (that is, they are diagnosed with disease, receive treatment and have a high level of symptoms and a further increased exacerbation rate), and may transition to **Controlled**, **Partially controlled**, **Exacerbation** or **Dead**.
- **Dead:** this is an absorbing state that patients transition to on death.

The health states defined in the model are named to reflect the 3 levels of symptom control which are used in asthma (fully controlled, partially controlled, uncontrolled) as outlined in the Global Initiative for Asthma (GINA).

However, transitions between symptom states can be ‘switched off’ to model fewer levels of control and can be renamed to model different levels of disease severity which have different exacerbation rates. Note that the EAG considered the four levels of COPD severity (GOLD 1, 2,3,4) when modelling a COPD population by a weighted average of GOLD 3 and 4 within the uncontrolled state, considering GOLD 2 as the partially controlled state and GOLD 1 as the controlled state (see clinical parameters outlined in section 6.2.3). This demonstrates the flexibility and adaptability of the model across different lung diseases.

The diagnostic decision tree (Figure 2) is used within the **Testing** state to distribute the population into starting states in the management phase. The tree splits the population of people with symptoms who need objective testing for lung conditions into those with disease, and those without. If spirometry is available for the patient to have, they have it, with the possible outcomes of a positive test, negative test, or no result available (for example, if the test is not performed correctly, or if the algorithm cannot provide interpretation). If spirometry is not available, or if no result is available, for asthma, an alternative test (serial peak flow measurement) is offered, which may be used to diagnose the condition. If these tests are negative, there is one final testing option. Each patient can only visit the **Testing** state and pass through the testing decision tree once, and at the terminal nodes of the tree, patients end up with one of four outcomes:

1. They have the disease and are treated (true positives).
2. They have the disease and are not treated (false negatives).
3. They do not have the disease but are treated as if they do (false positives).
4. They do not have the disease and are not treated (true negatives).

From here, patients move into the management phase of the Markov model. Although they may still have symptoms, true negatives move into the **No disease** state, where they incur no costs and their utilities are consistent with

the baseline for their age and sex. Further testing needed for this group, if they remain symptomatic, is beyond the scope of this EVA topic. To account for the likelihood of an imminent exacerbation in the false negative group, they move into the **Disease, untreated** state, and (in the base case) have the same likelihood of an exacerbation as those in the **Uncontrolled** state. Those who have a true positive diagnosis are split between the **Controlled**, **Partially controlled** and **Uncontrolled** states (based on the results from the Annual Asthma Survey, Asthma UK 2020) and incur costs for appropriate treatment. Those with false positive diagnoses will move into the "**No disease, but treated**" state, incurring costs for management of a lung condition they do not have, and receiving the utility decrement associated with unnecessary treatment (potentially inhaled steroids). Transitions between the levels of disease control are guided by the literature.

6.2.2 Model assumptions

Several assumptions have been made in developing the model:

- In the model, patients may die or suffer an exacerbation while in the **Undiagnosed**, **Disease, untreated** or **Undiagnosed but treated** states. It is assumed that once in the **Exacerbation** state, diagnosis is achieved by other means (assume included in the exacerbation costs) and patients move to the management phase. This is consistent with NG245, and an Expert suggested that a period of around 6 weeks would be needed after an exacerbation before testing could be performed (Appendix D2), so the EAG considers it reasonable that these patients take an alternative pathway. Therefore, patients cannot return to the **Undiagnosed** states, or **Disease, untreated** from the **Exacerbation** state.

- No other adverse events (except exacerbation and mortality) are included in the modelling. Within NG115, the committee advised that adverse events for those with COPD may include cardiac arrest, syncope, ventricular tachycardia, myocardial infarction, atrial fibrillation or flutter, angina, stroke, heart failure, pneumonia, constipation, dry mouth, and

urinary retention. However, the EAG note a lack of long-term data, and therefore no evidence that any specific technologies can demonstrate a reduction in any of these events. Additional adverse event states could be added to the economic model in future should more data become available.

- Patients may only pass through the **Testing** state once (spending a single cycle there). Although some patients may have a true negative diagnosis but remain symptomatic and undergo further testing, it is assumed that this is beyond the scope of this topic.

- Different levels of symptom control were included in the model, but the natural history and progression of the disease over time were not. The EAG recognise that diagnosing disease earlier, when the disease is less severe may have an impact on symptom control down the line. This may then lead to further economic impact, but these factors are not captured in the current conceptual economic model. If further data becomes available to inform event rates for different disease severity, this could be modelled in the future.

- The EAG also did not incorporate the risk of exacerbation or death while the patient is in the temporary “testing” state. This is a limitation of the approach taken which is trying to model waiting times, diagnostic accuracy and management within a single model structure. The impact of this is likely to be small because the time spent in this state is small and applies equally to both intervention and comparator arms.

- It is assumed that patients with a false positive result who do not have the disease will be treated as if they do and will be placed on inappropriate treatment. This has two impacts in the economic model: 1) it adds a treatment cost but is unlikely to resolve their symptoms, and 2) it may cause harm (reduce quality of life) especially in a younger population being treated with inhaled corticosteroids for a prolonged period. There is

uncertainty associated with the latter; however, this is addressed in sensitivity analysis.

- The model does not explicitly consider the use of biologics in a population with severe difficult-to-treat asthma. However, this is considered indirectly within sensitivity analysis by increasing the management costs and adjusting utilities within states that include treatment. The EAG also notes a limitation of the model in that it does not account for inappropriate use of such treatment in a mild asthma population.
- The costs of different severities of exacerbation are modelled as a weighted average (Table 28) and applied to transitions into the **Exacerbation** state. In the base case it is assumed that 95% of those within the exacerbation state leave that state within 1 month before transitioning into other management (fully controlled, partially controlled, uncontrolled) states. Therefore, occupancy costs are not applied. On the other hand, quality of life is applied on the occupancy of the state.
- Utilities of the general population are read into the model (as an input table) which enables a baseline utility to be applied based on the age and ratio of males to females in the starting cohort. However, the input utility table only includes data for those aged 16 and over. Therefore, for children under 16, the baseline utility of a 16-year-old has been assumed. The EAG note that only utility and standardised mortality rates vary by age in the model. Therefore, applying utility values derived from populations under 16 years old, if available, would have limited impact on results because they are applied in both comparator and intervention arms.
- Cohorts of adults and children are modelled separately to enable illustration of uncertainties. For the child population, which uses a minimum starting age of 6 years old, a maximum time horizon of 10 years is allowed, at which point they would need to be modelled as an adult cohort, for which the uncertainties would be similar to those modelled as an adult cohort from the outset.

- Utilities applied in the **Exacerbation** state are those used in NG245, adjusted using a utility multiplier derived from the ratio between exacerbation and controlled utilities from Zafari et al. 2014. NG245 used an individual patient simulation which gave more flexibility than the cohort Markov model developed here which does not retain history of where patients have transitioned from. The application of a utility decrement based on the utility in the previous state would be a preferred approach to using a single multiplier for the **Exacerbation** state but can only be applied where the utility in the previous state is known. Although a limitation, the simpler cohort approach taken for this early value assessment is appropriate, given that the aim of the conceptual economic modelling is not to reach a definitive conclusion on the cost-effectiveness of the interventions, but to explore the plausibility of the interventions being cost-effective and to identify gaps for future evidence generation. Individual patient simulations could be used in future to better model this, and other factors such as the impact of previous exacerbations on risk of future exacerbations.
- NG115 states that additional tests should be carried out alongside spirometry to diagnose COPD, as considered appropriate. However, for easy generalisability of the model between conditions, extra tests have not been modelled. These tests could include: sputum culture, serial home peak flow measurement, ECG and serum natriuretic peptides, echocardiogram, CT scan of the thorax, serum alpha-1 antitrypsin, and transfer factor for carbon monoxide. A limitation around modelling these additional tests would be the likelihood that there may be little difference in their use between arms. That is, using one of the interventions in scope may not influence the use of any additional tests. There are also many possible combinations of tests, which would be difficult to model on a cohort-basis.
- It is assumed that those with the disease have an increased mortality risk (applied using a hazard ratio) compared to those without the disease. The

EAG has assumed that this may differ across levels of disease control and exacerbation.

- Rates of exacerbation and death from health states containing an **Undiagnosed** population, who are awaiting testing, are calculated based on the prevalence of the disease. For example, for a disease prevalence of 59%, the rates of exacerbations and death associated with disease are applied to 59% of the cohort in the state (those who do have the disease). For the remaining 41% of the population, the standard mortality rate given their age and sex is used. For that 41% of the cohort, we also assume no rate of exacerbation (those without the disease cannot have an exacerbation). For the **Undiagnosed, awaiting objective testing** state, the EAG assumes the population with the disease will experience both exacerbations and mortality at the same rate as those in the **Uncontrolled** state. For the **Undiagnosed, and treated** state, the rates are instead equivalent to those in the **Controlled** state.
- For those with no disease who have been given treatment (inappropriately) after a false positive diagnosis, the model assumes no rate of exacerbation and uses the standardised mortality, based on their age and sex.

6.2.3 Clinical parameters

The clinical parameters of the conceptual economic model for asthma (separated by adults and children) and COPD are described in Table 26. The EAG note that several Experts in attendance at the scoping workshop highlighted that diagnostic imaging is used for the definite diagnosis of restrictive lung conditions (such as IPF) rather than spirometry. They also advised that for patients with suspected disease, changes in spirometry may identify those who require additional testing and therefore results from home testing may be applicable to that population. Due to the lack of data available for the EAG within this assessment, no economic modelling was conducted for restrictive lung disease. The general structure and assumptions of the EAG economic model could be adapted and applied in a restrictive lung disease population where data becomes available in future.

Table 26: Economic modelling: clinical parameters for asthma population

Variable [variable name in economic model]	Value (asthma: adults)	Value (asthma: children)	Value (adults: COPD)	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
Number of patients (starting population) [cohort_n]	1,000	Assumed same as asthma adults	Assumed same as asthma adults	Assumption. This number represents the number of patients who have suspected disease who are eligible for diagnostic spirometry.	For context, the Asthma and lung (2025) survey stated range between 2,500 (Northamptonshire Integrated Care System; GP practices not reported) and 28,742 (Lancashire + South Cumbria; across 196 GP practices) adults across the last financial year. No values of number of spirometry tests were available for paediatric population.
Age [start_age]	30	6	50	Expert opinion (Appendix D3). Adults (COPD): Lambe et al. 2019	The EAG did not use HES Admitted Patient Care data as this reflects only patients requiring hospital admission with exacerbation (representing the more severe population only). Two Experts [providing insight to the GID-HTE10065 Digital technologies for asthma self-management topic] advised that diagnosis and management will vary across different age bands in children and highlighted that BTS/SIGN/NICE guidelines have different recommendations in children under 5, children aged 5 to 11 and people ages 12 and over. The EAG note that there was a lack of clinical evidence specific to these ages categorised, therefore the majority of clinical parameters were affected by age (exception being standardised mortality which was available for all ages, and baseline utilities which were available for 16 years and older). However, the EAG note that the model could be adapted for different age groups in future economic modelling. Younger and older starting age (older only in a paediatric cohort with suspected asthma) were considered in sensitivity analysis.
Male (%) [male_prop]	38%	50%	53%	Adults (asthma): Sunjaya et al. 2025 which reported results from retrospective study of spirometry data from primary care clinics in UK between 2015 and 2019. Children (asthma): One expert advised that asthma only has a female predominance in adults (Appendix D3). Adults (COPD): Whittaker et al. 2022; Lambe et al. 2019.	The EAG note that in the economic model, changes to the proportion of males and females in the cohort only impact on the baseline utility and baseline standardised mortality. These would change in both intervention and comparator arm, and with only small differences introduced between arms by other parameters (for example, diagnostic accuracy of testing, and exacerbation rates), changing this is unlikely to impact economic modelling results.
Baseline prevalence of disease (%) [prev]	59%	Assumed same as asthma adults	Assumed same as asthma adults	Asthma: NG245 (2024)	Large uncertainty associated with this parameter, will depend on previous tests conducted, the setting in which the testing is applied. Experts have advised

Variable [variable name in economic model]	Value (asthma: adults)	Value (asthma: children)	Value (adults: COPD)	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
				COPD: Unknown: same value applied as asthma	that there is variability in diagnostic pathways and will have geographical variation depending on services available. Therefore, the EAG included this parameter within sensitivity analysis.
Transition rate from "Undiagnosed, waiting for objective testing" or "Undiagnosed, treated waiting for objective testing" to "Testing" [p_test_in_window] [test_window] applied in days Applied using exponential function.	63.2% diagnosed in 6 months	Assumed same as asthma adults	Assumed same as asthma adults	Howard (2023) which reported data from the Asthma + Lung study which found that of those diagnosed with a lung condition across 2 years (2021-2023) that 36.8% had waited more than six months for a diagnosis.	In the base case we kept this the same between intervention (digital technologies) and comparator (standard care) arms. In sensitivity analysis we varied the rate in the intervention arm only to model the potential impact of the technologies resulting in faster testing. The EAG acknowledge the limitation that the value used is total waiting time for diagnosis not testing. Experts considered waiting time could be anywhere between 6 weeks in primary care and 6 months if waiting for secondary care. The rate at which patients receive testing in the intervention arm (assuming that use of the technologies increases access to testing) was explored in sensitivity analysis.
Proportion moving from "Undiagnosed: waiting for objective testing" to "Undiagnosed: treated, waiting for objective testing" per cycle [p_undiag_treated]	25%	Assumed same as asthma adults	Assumed same as asthma adults	Expert opinion (Appendix D3)	There is a difference between NICE guidelines (NG245) and standard care practice in the NHS. This is explored in sensitivity analysis.
Annualised exacerbation rates (in "Controlled" state) [p_contr_exac]	0.195	0.175	0.409	Asthma: NG245 (2024) COPD: 0.38 (non-hospitalised) +0.029 (hospitalised) for GOLD 1 as reported in NG115.	
Annualised exacerbation rates (in "Partially controlled" state) [p_partcontr_exac]	0.199875	0.179375	0.414	Asthma: assumed 2.5% increase compared to controlled state (midway between fully controlled and uncontrolled) COPD: 0.39 (non-hospitalised) +0.024 (hospitalised) for GOLD 2 as reported in NG115.	Asthma: This is an area of uncertainty, therefore the EAG varied the proportion increase in exacerbations from the partially controlled asthma state to 5% in sensitivity analysis.
Annualised exacerbation rates (in "Uncontrolled" state) [p_uncontr_exac]	0.20475	0.18375	0.5588	Asthma: assumed 5% increase compared to controlled state COPD: Weighted average across 0.499 (non-hospitalised) +0.052 (hospitalised) which applied to 23.6% of patients with GOLD 3 and 0.599 (non-hospitalised) +0.082 (hospitalised) which applied to 1.5% patients with GOLD	The Experts highlighted to the EAG a UK primary care study which found that exacerbations increased the risk of future exacerbations (Whittaker et al. 2022). One Expert also highlighted a study which identified a number of predictive factors of future asthma attacks using UK electronic medical records (Blakey et al. 2017), where 4% had 2 asthma attacks and 2% had 3 or more asthma attacks in the baseline year. However, the EAG took a pragmatic decision for this EVA and chose to model a single exacerbation health state. In

Variable [variable name in economic model]	Value (asthma: adults)	Value (asthma: children)	Value (adults: COPD)	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
				4 as reported in NG115.	sensitivity analysis the EAG explored changes in the exacerbation rate for the controlled arm states. This affects results and from this infer if a plausible increasing risk of subsequent exacerbations is a research priority. Similarly, sensitivity analysis explores if the increased risk of exacerbations in the uncontrolled state is a research priority.
Annualised exacerbation rates (in "Undiagnosed, treated" state) [p_undiag_treated_exac] calculated in model using [prev], and [p_contr_exac]	Calculated in R: p_undiag_treated_exac = prev * p_contr_exac	Assumed same as asthma adults	Assumed same as asthma adults	Calculated field.	This is a calculated field which considers the prevalence of disease and assumes that that proportion receiving treatment while awaiting objective testing will see benefit from being on treatment in the form of reduced exacerbations (the remaining patients in the undiagnosed, treated state who do not have disease will not experience any exacerbations).
Annualised exacerbation rates (in "Undiagnosed, waiting for objective testing testing" state) [p_undiag_test_exac] calculated in model using [prev], [p_uncontr_exac]	Calculated in R: p_undiag_test_exac = prev * p_uncontr_exac	Assumed same as asthma adults	Assumed same as asthma adults	Calculated field.	This is a calculated field which considers the prevalence of disease and the annualised exacerbation rates in the uncontrolled state to enable modelling of impact of delayed testing (and therefore associated treatment). This applies to the testing state itself to account for the 1-month cycle length (within which events may occur).
Annualised exacerbation rates (in "Disease, untreated" state) [p_untreat_exac]	Assumed same as uncontrolled	Assumed same as uncontrolled	Assumed same as uncontrolled		Set to the same as transition from uncontrolled state in base case.
Probability of spirometry being available [p_Spiro]	0.33	0.33	1.00	Assumption.	Asthma: Where spirometry is unavailable alternative/further tests may be applied (see Figure 2). COPD: in line with NG115, spirometry must be used for diagnosis, by setting availability of spirometry to 100%, alternative testing is effectively switched off. Waiting for spirometry for COPD diagnosis is still accounted for in the transition rates from Undiagnosed to Testing.
Diagnostic accuracy: Testing Spirometry (Comparator) [sensitivity_Spiro] [specificity_Spiro]	Sensitivity: 0.37 Specificity: 0.96	Sensitivity: 0.68 Specificity: 0.76	Assumed same as asthma adults	Asthma adults: NG245 (2024) Table 4. Asthma children: NG245 (2024) Table 7 (noting typographical error in Table 4 in NG245) COPD: Assumed the same as for asthma adults.	The EAG note that this is a particular evidence gap and that diagnostic performance of standard care for COPD is likely to be higher (since spirometry is accepted as the diagnostic test for COPD). The EAG note that data from the SPIRO-AID trial has been considered in sensitivity analysis (provided academic in confidence; aligns well to the decision problem comparing diagnosis in NHS primary care with and without the use of ArtiQ.Spiro against a secondary care expert reference standard, see Diagnostic accuracy of initial diagnosis).
Diagnostic accuracy: Testing Spirometry (Intervention)	Sensitivity: 0.47	Sensitivity: 0.78	Assumed same as	Assumption.	The EAG note that this is a particular evidence gap and therefore the EAG assumed 10%

Variable [variable name in economic model]	Value (asthma: adults)	Value (asthma: children)	Value (adults: COPD)	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
[sensitivity_Spiro] [specificity_Spiro]	Specificity: 0.96	Specificity: 0.76	asthma adults		increased sensitivity in the intervention arm (explored further in sensitivity analysis). The EAG note that data from the SPIRO-AID trial (provided academic in confidence) has been considered in sensitivity analysis.
Diagnostic accuracy: Alternative testing if spirometry is unavailable or the result is unavailable **PEFv** [sensitivity_NS] [specificity_NS]	Sensitivity: 0.15 Specificity: 0.97	Sensitivity: 0.50 Specificity: 0.72	N/A	Asthma: NG245 (2024) COPD: Spirometry is primary diagnostic (NG115); unclear on additional testing – assumed same as asthma in base case.	Within the decision tree (Figure 2) alternative testing is only required when spirometry is unavailable. Noting that in the base case the probability of spirometry being available is 33% (therefore 67% of those undergoing objective testing will require alternative testing due to spirometry being unavailable).
Diagnostic accuracy, further testing in standard care [sensitivity_FT] [specificity_FT]	Sensitivity: 0.91 Specificity: 0.86	Sensitivity: 0.79 Specificity: 0.87	Assumed same as asthma adults	Asthma: NG245, testing strategy 5 used for both adults and children respectively. COPD: Spirometry is primary diagnostic (NG115); unclear on additional testing – assumed same as asthma in base case.	EAG acknowledge the potential for double counting by applying diagnostic accuracies of a sequence of tests to a single test.
Proportion of spirometry tests for which a result is not available [p_Spiro_RU]	0%	Assumed same as asthma adults	Assumed same as asthma adults	Assumption	Limited evidence on this outcome. This may include proportion where spirometry is not appropriate for the patient, or where a successful spirometry reading cannot be achieved. The EAG note that technologies used by the patient in a home setting may have a higher proportion of results not available when compared to standard care (conducted in a primary care or community setting by a healthcare professional).
Transition rate from exacerbation state [p_dis_in_window] [dis_window]	95% in 1 month	Assumed same as asthma adults	Assumed same as asthma adults	NG245 (2024)	Simplification of 28-day duration of exacerbation applied in NG245 for utilities (time to recover from exacerbation). Because of the approach taken to model transitions from this state, the EAG cannot apply a 100% transition from the state, so assumes most exacerbations will be resolved in 1 month. Longer stays can be modelled in sensitivity analysis.
Proportion with true positive diagnosis starting in each level of control, and transitioning back to each level of control from Exacerbation [p_contr] [p_partcontr] [p_uncontr]	Controlled: 20.7% Partially controlled: 39.2% Uncontrolled: 40.1%	Assumed same as asthma adults	Controlled: 19.3% Partially controlled: 55.6% Uncontrolled: 25.1%	Asthma: Asthma UK, 2020 COPD: based on 19.3% GOLD 1, 55.6% GOLD 2, 25.1% GOLD 3 or 4 (NG115)	The EAG was unable to source UK audit data for this parameter.
Transition rates from controlled asthma state [p_contr_partcontr] [p_contr_uncontr]	To Partially controlled: 0.50 (assumed)	Assumed same as asthma adults	To Partially controlled: 0.0876	Asthma: Van de Hei et al. 2023. COPD: Lambe et al. 2019	Uncertainty associated with these transitions. Considered in sensitivity analysis.

Variable [variable name in economic model]	Value (asthma: adults)	Value (asthma: children)	Value (adults: COPD)	Source	EAG commentary on availability, quality, reliability and relevance of the source/s
	To Uncontrolled: 0.006		To Uncontrolled: 0		
Transition rates from partially controlled asthma state [p_partcontr_contr] [p_partcontr_uncontr]	To Controlled: 0.50 (assumed) To Uncontrolled: 0.006	Assumed same as asthma adults	To Controlled: 0.051 To Uncontrolled: 0.0362	Asthma: Van de Hei et al. 2023. COPD: Lambe et al. 2019	Uncertainty associated with these transitions. Considered in sensitivity analysis.
Transition rates from uncontrolled asthma state [p_uncontr_contr] [p_uncontr_partcontr]	To Controlled: 0.025 To Partially Controlled: 0.025	Assumed same as asthma adults	To Controlled: 0 To Partially Controlled: 0.9123	Asthma: Van de Hei et al. 2023. COPD: Lambe et al. 2019	Uncertainty associated with these transitions. Considered in sensitivity analysis.
Mortality, general population [qsmr]	Age and sex specific	Age and sex specific	Age and sex specific	ONS Life tables 2021 to 2023 (Office for National Statistics, 2025);	This is adjusted by the HR for mortality for those with asthma or exacerbation in applicable states and is applied to the proportion of patients in the undiagnosed states who do not have the disease and applied to all patients in the no disease states.
Mortality, people with Controlled disease, or in the Undiagnosed, being treated state (HR applied to standardised mortality of general population) [HR_mort_contr]	HR = 1.25	HR = 1.77	HR=1.00	Asthma: NG245 (2024) COPD: Assumption. NG115 (2018) stated HR of 0.83, however the EAG considers it implausible that a person with COPD has a lower risk of mortality than someone with no disease.	This applies to the controlled state, and the proportion of patients in the Undiagnosed, and treated state who do have the disease. This reflects the increased mortality risk from having disease.
Mortality, people with Partially controlled disease (HR applied to standardised mortality of general population) [HR_mort_partcontr]	HR = 1.25	HR = 1.77	HR=1.51	Asthma: Assumption that partially controlled asthma is associated with the same risk of death as controlled asthma COPD: NG115 (2018)	This applies to the partially controlled state and reflects the increased mortality risk from having disease.
Mortality, people with Uncontrolled disease, or in the Undiagnosed, awaiting objective testing state, or Disease untreated states (HR applied to standardised mortality of general population) [HR_mort_uncontr]	HR = 1.25	HR = 1.77	HR=3.27	Asthma: Assumption COPD: NG115 (2018), weighted average of HR for severe and very severe disease (GOLD grouping 3 and 4) based on proportions in each group	This applies to the uncontrolled state, the proportion of patients in the Undiagnosed, awaiting objective testing state who do have the disease, and the disease untreated state. This reflects the increased mortality risk from having disease that is not being properly controlled by treatment.
Mortality, people having an exacerbation (HR applied to standardised mortality of general population) [HR_mort_exac]	HR = 1.3125	HR = 1.8585	HR=3.44	Asthma: Assumption COPD: Assumption	Assumed 5% increase to HR for mortality from Uncontrolled state.
Transition probability between "No disease, but treated" and "No disease" [p_false_pos]	0	0	0	Assumption	This enables modelling of "incorrect diagnoses". Set to 0% in base case but increased in sensitivity analysis.

Abbreviations: BTS, British Thoracic Society; COPD, chronic obstructive pulmonary disease; EAG, External Assessment Group; GOLD, Global Initiative for Chronic Obstructive Lung Disease; HES, Hospital Episode Statistics; HR, hazard ratio; ICS, Inhaled corticosteroids; NG, NICE Guidelines; ONS, Office of National Statistics; PEFv, peak expiratory flow variability; SIGN, Scottish Intercollegiate Guidelines Network

6.2.4 Resource use and cost parameters

Technology costs were only provided for four of six technologies in scope, see Table 27 (detailed cost breakdown summarised in Appendix C2). The two technologies where no prices were provided by the company were not included in economic modelling; however, the EAG considered technology pricing within sensitivity analysis. Where the technology could only be used with a specific spirometer brand, the EAG applied costs supplied by the company or applied costs from NHS Supply Chain where available. Only one company provided estimated integration costs (£5,000), which the EAG applied to all technologies (assuming that this covers IT set up, usernames, access to results in a portal, and so on) which was shared across 2,100 patients; approximately £2.38 per patient in the intervention arm. This is in line with NG245 (2024), assuming a spirometer would have a lifetime of seven years and would be used 2,100 times over that period. The integration costs applied were therefore £2.38 per patient. At stakeholder consultation ArtiQ.Spiro stated that there is no direct integration cost for their technology as the users already have their spirometer installed and no additional software installation or integration is needed. The user only needs to enter a company-provided username and keycode. ArtiQ previously suggested that the £2.38 cost could be considered as part of a training cost (which the EAG assumes includes covering how the users would log in and use the software); therefore this additional cost was applied by the EAG.

For technologies used in a home setting (NuvoAir), the EAG assumed that 10% of users would require a tablet or mobile (assume £100) and additional monthly cost of mobile internet connection (£21) was applied; with the remaining 90% of users being able to use their own device. This approach would incur an additional £12.10 per patient that was added to the technology costs at the diagnostic testing phase (with the assumption that the patient would return the mobile device to the healthcare setting when they no longer use the technology to support diagnosis, although reuse of the device is not considered). The EAG considered inclusion of these costs to address the

barriers to access to these technologies and equity concerns around digital exclusion. These additional costs were removed in sensitivity analysis to determine the potential impact on outcomes.

Costs charged by the companies for training and maintenance were converted into per patient costs, assuming that the technology was used in 300 patients per year. The EAG did not account for staff time to attend training within cost estimates because of variability in reporting between companies, the different staff that may be involved, the different patient groups in which each technology would be used and the number of practices that would share this cost. It would therefore be difficult to attribute a training cost per patient. However, a simple calculation assuming two Band 5 practice nurses (at a cost of £53 each per hour) attend a 2-hour training session, would result in a minimal (approximately £0.70) additional cost for each of the 300 patients using the intervention each year. The total cost for each technology is varied enough in sensitivity analysis to cover this increase.

In terms of staff time the EAG assumed 30 minutes of a practice nurse for measurement, and 10 minutes for interpretation in standard care. The EAG assumed that 5 minutes of measurement and 5 minutes of interpretation time were saved when using ArtiQ.Spiro, MIR Spiro, EasyOne Connect and GoSpiro (clinic) technologies. When using LungHealth no change to the measurement time was assumed when compared to standard care (as this relies on existing spirometry measurements) however 20 minutes additional staff time was assumed to guide the patient through a questionnaire (which the EAG assumes would include interpretation of results. Staff time associated with measurement and interpretation were removed completely for NuvoAir, which represents a service (cost assumed within the cost per patient provided by the company). Staff costs associated with practice nurse (Band 5) time for initial measurement and interpretation were applied using hourly rates from the same year as all costs, where necessary, were inflated to 2024 (Jones et al. 2025).The EAG note that assuming that interpretation could be conducted by a lower band qualified nurse (Band 4) in the intervention arm

would result in reduction of only £0.75 in per patient costs in the technology arm (5 minutes Band 5 nurse £4.42, 5 minutes Band 4 nurse £3.75; difference £0.75). This small change in per patient costs is covered by the range of technologies costs applied in sensitivity analysis (see section 6.2.7).

The EAG also applied generic cost of a spirometer from NG245 where additional hardware was required and where the software technology was considered compatible with multiple spirometer manufacturers, assuming (as in NG245) each spirometer would be used by 2,100 patients over a 7-year lifetime.

The EAG assumed that the additional cost of a GP appointment to receive the diagnosis would be applicable to all arms (intervention and comparator) and therefore was omitted as it would cancel out between arms.

Additional costs associated with the diagnostic pathway, management pathway and treatment of adverse events (exacerbations) used in the economic modelling (inflated to the latest available year using the CCEMG – EPPI Centre Cost Converter) applied across asthma and COPD populations are described in Table 28, Table 29 and Table 30.

Table 27: Economic modelling: technology costs

Costs per patient*	Standard care	ArtiQ.Spiro	LungHealth	MIR Spiro	EasyOne Connect	GoSpiro (clinic)	NuvoAir
Technology (per patient)	-	£3.00	£15.00	NR	NR	£3.73	£149
Spirometer (device), per patient	£0.62	£0.69	£0.62	[redacted]	[redacted]	-	-
Spirometer (calibration), per patient	£0.13	£0.13	£0.13	[redacted]	[redacted] (EasyOne spirometers do not require calibration)	£0.07	-
Spirometer (consumables), per patient	£1.16	£1.16	£1.16	[redacted]	[redacted]	£2.43	-
Mobile phone and internet plan	-	-	-	-	-	-	£12.10
Integration	-	£2.38	£2.38	£2.38	£2.38	£2.38	£2.38
Training	-	-	-	-	-	£0.15	-
Staff time (training patient)	-	-	-	-	-	-	
Staff time (measurement)	£26.50	£22.08	£26.50	£22.08	£22.08	£22.08	- (included in costs)
Staff time (consultation)	-	-	£17.66	-	-	-	-
Staff time (interpretation)	£8.83	£4.42	-	£4.42	£4.42	£4.42	- (included in costs)
Total	**£37.24**	**£33.86**	**£63.45**	**Not included in economic modelling**	**Not included in economic modelling**	**£35.26**	**£163.48 (alternatively: £151.38 without mobile device/internet)**

Key: *Additional cost breakdown available in Appendix C2.
Abbreviations: NR, not reported

Table 28: Economic modelling: cost parameters for tests associated with diagnosis

Parameter	Value (adults: asthma)	Value (children: asthma)	Value (adults: COPD)	Source	Comment
Spirometry, standard care [c_Spiro]	£37.24	Assumed same as asthma adults	Assumed same as asthma adults	See Table of technology costs (Table 27)	Assuming 30 minutes practice nurse for measurement and 10 minutes for interpretation.
Spirometry, intervention [c_Spiro]	£63.45	Assumed same as asthma adults	Assumed same as asthma adults	Pricing from LungHealth applied in base case	ArtiQ and GoSpiro had lower per patient costs and NuvoAir had costs four times higher than the comparator. Because of the small difference in QALYs between arms, using these costs in the base case would cause big changes in the ICER, and limit the ability of the EAG to interpret results of univariate sensitivity analysis to explore key drivers and areas of uncertainty in the economic model. Costs of other technologies will be applied in sensitivity analysis.
PEFv (standalone) [c_peak_flow]	£28.23	Assumed same as asthma adults	£0	Asthma: NG245 Table 29 stated £25.78 and assumed 20 minutes staff time. EAG inflated from 2022 to 2024 price year.	
Further testing [c_FT]	£196.56	Assumed same as asthma adults	Assumed same as asthma adults	Asthma: NG245 diagnostic report (2024) Table 28 which lists bronchial challenge with methacholine or mannitol as the most expensive testing as occurs in a hospital setting (£179.49).	Will be varied in sensitivity analysis to use lower cost testing.

Parameter	Value (adults: asthma)	Value (children: asthma)	Value (adults: COPD)	Source	Comment
				The EAG inflated these costs (from 2022) to 2024 prices.	

Abbreviations: COPD, chronic obstructive pulmonary disease; EAG, External Assessment Group; ICER, Incremental Cost-Effectiveness Ratio; NG, NICE Guidelines; PEFv, peak expiratory flow variability; QALY, Quality Adjusted Life Year

Table 29: Economic modelling: cost parameters for treating and managing disease

Parameter	**Value (adults: asthma)**	**Value (children: asthma)**	**Value (adults: COPD)**	**Source**	**Comment**
Monitoring cost, per patient, per year [c_monitoring]	£29.85	Assumed same as asthma adults	Assumed same as asthma adults	Asthma: NG245 (2024) stated value without FeNO (£27.26 per year excluding FeNO - inflated to £29.85; weighted average, assuming 1 practice nurse appointment for 80% of patients, 2 appointments for 15%, and an outpatient visit for 5%). EAG applied inflation to 2024 price year COPD: Assumed same as Asthma adults.	Different weightings are considered in range of values tested within sensitivity analysis for monitoring costs.
Treatment, (Undiagnosed, and treated, waiting for objective testing, and controlled states) [c_treatment_contr]	£45.14	£60.50	£32.47	Asthma: NG245 (2024) For adults: assuming 0.53 actuations per day, and that adults go straight onto ICS/LABA combined. For children assuming 1.11 ICS actuations and 1.01 SABA actuations per day; and that children were treated with ICS and separate SABA until adulthood. Assume 2024 price year, no inflation applied. C COPD: Used treatment cost per cycle for mild COPD (£26) stated in NG115 (inflated from 2018 to 2024 prices).	Switch to adulthood is explored in sensitivity analysis (children modelled with starting age of 6 years and management for 10 years, followed by the adult model starting at 16 years).
Treatment, (Partially controlled state) [c_treatment_partcontr]	£45.14	£60.50	£34.97	Asthma: NG245 (2024). For adults: assuming 0.53 actuations per day, and that adults go straight onto ICS/LABA combined. For children assuming 1.11 ICS actuations and 1.01 SABA actuations per day; and that children were treated with ICS and separate SABA until adulthood. Assume 2024 price year, no inflation applied. COPD: Used treatment cost per cycle for moderate COPD (£28) stated in NG115 (inflated from 2018 to 2024 prices).	Switch to adulthood is explored in sensitivity analysis (children modelled with starting age of 6 years and management for 10 years, followed by the adult model starting at 16 years).
Treatment, (Undiagnosed, waiting for objective testing, Disease, untreated, and uncontrolled states) [c_treatment_uncontr]	£45.14	£60.50	£247.99	Asthma: NG245 (2024). For adults: assuming 0.53 actuations per day, and that adults go straight onto ICS/LABA combined. For children assuming 1.11 ICS actuations and 1.01 SABA actuations per day; and that children were treated with ICS and separate SABA until adulthood. Assume 2024 price year, no inflation applied. COPD: Used weighted sum of cost per cycle for severe (£189) and very severe (£350) COPD. Using proportions in GOLD	Switch to adulthood is explored in sensitivity analysis (children modelled with starting age of 6 years and management for 10 years, followed by the adult model starting at 16 years).

Parameter	Value (adults: asthma)	Value (children: asthma)	Value (adults: COPD)	Source	Comment
				status 3 (23.59%) and 4 (1.49%) stated in NG115. (0.2359/0.2508)*189 + (0.0149/0.2508)*350 = £201.38 (inflated from 2018 to 2024 prices).	

Abbreviations: COPD, chronic obstructive pulmonary disease; EAG, External Assessment Group; FeNO, fractional exhaled nitric oxide; GOLD, Global Initiative for Chronic Obstructive Lung Disease; ICS, inhaled corticosteroids; LABA, long-acting beta agonist; NG, NICE Guidelines; SABA, short-acting beta agonist

Table 30: Economic modelling: cost parameters for treating and managing exacerbations

Parameter	Value (adults: asthma)	Value (children: asthma)	Value (adults: COPD)	Source	Comment
Cost of mild or moderate exacerbation [c_exac_mild] [c_exac_mod]	£46	Assumed same as asthma adults	£97.42	Asthma: NG245 (2024) stated £42. The EAG inflated from 2022 to 2024 price year. COPD: NG115 (2018) stated £78 for non-hospitalised and £2111 for hospitalised exacerbations respectively. The EAG inflated to 2024 price year.	
Cost of severe exacerbation [c_exac_severe]	£183.11	Assumed same as asthma adults	£2,636.48	Calculated field. Asthma: using information from NG245. For severe exacerbations, average cost is £102. Assume that all exacerbations include an initial GP visit and a follow up with GP/nurse practitioner (50:50 split). GP visit cost £38, nurse practitioner visit £16.39 (NG245 Table 19). Total cost of severe exacerbation calculated as £102 + £38 + (0.5*£38) + (0.5*£16.39) = £167.20, EAG inflated to 2024 prices. COPD: Cost of £2,263 stated in Lambe et al. 2019 for severe exacerbations; EAG inflated to 2024 prices.	In COPD costs are much higher but in line with values used in other economic models (for example: Lambe et al. 2019 used £2,263 for severe exacerbations, which would be £2767.81 if inflated to 2024 prices)
Weighted average cost of exacerbation (from controlled states) [c_treat_exac]	Calculated in R: (p_treated_exac_mild * c_exac_mild) + (p_treated_exac_mod * c_exac_mod) + (p_treated_exac_severe * c_exac_severe) Where p_treated_exac_mild = p_treated_exac_mod = 0.5 * (1 - p_treated_exac_severe)	Assumed same as asthma adults	Assumed same as asthma adults	Calculated variable. Asthma: Assuming 24% severe [p_treated_exac_severe] as stated in NG245 guideline for severity in people treated with asthma, and the rest split between 50% moderate [p_treated_exac_mod] and 50% mild [p_treated_exac_mild]. COPD: proportion of severe exacerbations [p_treated_exac_severe] computed as a weighted average of the proportion of exacerbations with hospitalisations (based on baseline exacerbation rates and proportions of patients in each GOLD stage) according to NG115. The rest split between 50% moderate [p_treated_exac_mod] and 50% mild [p_treated_exac_mild].	Uncertainty associated with this value (and proportion attending hospital). Therefore, cost will be explored within sensitivity analysis.

Parameter	Value (adults: asthma)	Value (children: asthma)	Value (adults: COPD)	Source	Comment
Weighted average cost of exacerbation (uncontrolled and undiagnosed states) [c_untreat_exac]	Calculated in R: (p_untreated_exac_mild * *c_exac_mild)* + *(p_untreated_exac_mod* * c_exac_mod) + (p_untreated_exac_severe * *c_exac_severe)* Where p_untreated_exac_mild = p_untreated_exac_mod = 0.5 * (1 - p_untreated_exac_severe)	Assumed same as asthma adults	Assumed same as asthma adults	Calculated variable. Asthma: Assuming 31% severe [p_untreated_exac_severe] as stated in NG245 guideline for severity in people untreated with asthma and the rest split between 50% moderate [p_untreated_exac_mod] and 50% mild [p_untreated_exac_mild]. COPD:ratio between p_treated_exac_mild and p_untreated_exac_mild for asthma adults applied to p_untreated_exac_mild for COPD. The rest split between 50% moderate [p_treated_exac_mod] and 50% mild [p_treated_exac_mild].	As above

Abbreviations: COPD, chronic obstructive pulmonary disease; EAG, External Assessment Group; GOLD, Global Initiative for Chronic Obstructive Lung Disease; NG, NICE Guidelines

6.2.5 Health state utilities

Utility parameters used in asthma (adults and children) and COPD populations are described in Table 31.

Table 31: Economic modelling: utility parameters in disease population

Parameter	Value (adult: asthma)	Value (children: asthma)	Value (adult: COPD)	Source	Comment
Utilities, baseline [u_baseline]	Age and sex specific	Age and sex specific	Age and sex specific	Asthma: NICE Decision Support Unit (Hernández Alava et al., 2022) COPD: Assumed as asthma	This is the baseline utility used in the model [u_baseline] to which other multipliers, increments and decrements are applied. Downloaded spreadsheet of values read into the economic model
Utility multiplier (controlled), applied in the Controlled state, and Undiagnosed, but treated, awaiting testing state [um_contr]	0.880	0.96	Assumed same as asthma adults	NG245 states that this accounts for all patients with persistent asthma-like symptoms at baseline, entering a diagnostic pathway for suspected disease	EAG assumes this applies to all patients, accounting for all patients being symptomatic at baseline, entering a diagnostic pathway for suspected disease. Asthma-like symptoms are assumed to have a similar negative impact on quality of life across all patients.
Utility multiplier (partially controlled), applied in the Partially controlled, and Testing states [um_partcontr]	0.8372	0.9133	0.7648	Asthma: NG245; Zafari et al 2014 COPD: Assumed same start point as Asthma and applied multiplier using data from NG115	Utility multiplier from NG245 for controlled asthma, further adjusted using utility multiplier derived using ratio between partially controlled and controlled utilities from Zafari et al 2014. Asthma (adults): 0.880*(0.900/0.946) Asthma (children): 0.96*(0.900/0.946) COPD: 0.88*(0.787/0.9056) For simplicity, the EAG has assumed that patients entering the testing state have partial control of their disease, to account for the split of patients who have and have not already been on treatment.
Utility multiplier (uncontrolled), applied in the Uncontrolled, Undiagnosed, awaiting testing states [um_uncontr]	0.7833	0.8545	0.6546	Asthma: NG245; Zafari et al., 2014 COPD: Assumed same start point as Asthma and applied multiplier using data from NG115	Utility multiplier from NG245 for controlled asthma, further adjusted using utility multiplier derived using ratio between uncontrolled and controlled utilities from Zafari et al 2014 (multiplier = 0.842/0.946). Asthma (adults): 0.880*(0.842/0.946) Asthma (children): 0.96*(0.842/0.946) COPD: Weighted average across GOLD 3 and GOLD 4 (0.88*(((0.236/0.251)*0.75)+((0.015/0.251)*0.647))
Utility multiplier (exacerbation) [um_exac]	0.6781	0.7398	0.6090	Asthma: NG245; Zafari et al 2014 COPD: Assumed utility of very severe COPD and considered the proportion where the patient was hospitalised.	Utility multiplier from NG245 for controlled asthma, further adjusted using utility multiplier derived using ratio between exacerbation and controlled utilities from Zafari et al 2014. Asthma (adults): 0.880*(0.729/0.946) Asthma (children): 0.96*(0.729/0.946) COPD: 0.647-(0.09*0.42)
Utility decrement: false positive diagnosis [ud_falsepos]	0	0	0	Asthma: assumption COPD: Johnson et al. 2021	Large uncertainty associated with this value; however, will only be applied in the "No disease Treated" state. Two Experts [providing insight to the GID-HTE10063 Digital technologies for asthma self-management topic] highlighted that most side effects would only affect patient on high dose inhaled steroids for a prolonged period; one Expert [redacted] advised that short term side effects include oral pharyngeal effects. The EAG identified a study (Kavanagh et al. 2019) which stated that misdiagnosis of asthma may delay alternative diagnosis, and long-term use of inhaled steroids may impact bone, muscle, psychiatric, cardiovascular, ocular and metabolic disease may also impact quality of life. Two Experts [providing insight to the

Parameter	Value (adult: asthma)	Value (children: asthma)	Value (adult: COPD)	Source	Comment
					GID-HTE10063 Digital technologies for asthma self-management topic] advised that the impact of an alternative missed diagnosis could be significant and may include restriction of activity unnecessarily which may impact health. One Expert [redacted] advised that there may be mental health repercussions and may impact future careers (for example military). Therefore, this is considered in sensitivity analysis.

Abbreviations: COPD, chronic obstructive pulmonary disease; EAG, External Assessment Group; GOLD, Global Initiative for Chronic Obstructive Lung Disease; NG, NICE Guidelines

6.2.6 Model validation

The EAG built a conceptual economic model for this EVA, rather than a fully parameterised economic model needed to support routine use guidance. The focus of the conceptual modelling was to identify key drivers and uncertainties; therefore, validation was mainly internal rather than external. This modelling approach enabled identification of which parameters the model results were most sensitive to, rather than whether the predictions were consistent with other analyses or data.

The EAG applied extreme value testing and document model validation using the AdViSHE tool (see Appendix B2). Two authors (RO, SG) reviewed the Markov traces to ensure that appropriate numbers of patients were transitioning to each health state (Appendix B3). Extreme value testing of probabilities, costs and utilities was also performed to check that results were plausible given inputs (SG, KK). The model was peer reviewed by an experienced health economist (LV). As part of external validation, the EAG checked the per patient cost associated with the comparator (standard care) which was micro-costed by the EAG (£39.62), against the total cost associated with bronchodilator reversibility used in the NG245 which was published in 2024 (£39.16); concluding these were consistent.

6.2.7 Presentation of results

Results of the economic modelling were reported separately by disease group. Model outputs included occupancies of states at the end of the time horizon, total costs, total quality-adjusted life years (QALYs), from which incremental costs, incremental QALYs and incremental cost-effectiveness ratios (ICERs) could be calculated. The incremental net monetary benefit (NMB) was also calculated using a willingness to pay threshold of £20,000/QALY.

To determine the key drivers from the economic modelling and to inform future data collection efforts, the EAG focused on univariate deterministic

sensitivity analysis. Univariate sensitivity analysis varied by disease group and population, Table 32.

Table 32: Summary of univariate sensitivity analysis by disease group and population

Parameter	Adults (asthma)	Paediatric (asthma)	Adults (COPD)	Source	Comment
Age	16, 40	9, 12	40, 60	Expert opinion (Appendix D3).	
Time horizon	2, 20 years	2, 5 years	2, 20 years	Assumption	Note that children cohort (starting age of 6) modelled for 10 years will then move to adult cohort (starting age of 16) where treatments and costs differ.
Disease prevalence	8%, 20%, 36%, 80%	8%, 20%, 36%, 80%	8%, 20%, 36%, 80%	Asthma: Darbà et al. 2021; 80% [NG245, 2024] COPD: assumed same as asthma	The EAG note that disease prevalence many vary by setting, therefore has tested both lower and higher values to determine impact on results.
Higher proportion of patients receiving objective testing within 6 months (intervention arm only)	70%, 75%, 80%, 85%	70%, 75%, 80%, 85%	70%, 75%, 80%, 85%	Assumption	Applied in the intervention arm, to model impact of the technologies increasing the rate at which objective testing can occur in the population.
Sensitivity of intervention technology (intervention arm only)	57%, 67%, 77%, 87%	57%, 67%, 77%, 87%	57%, 67%, 77%, 87%	Assumption	Applied 10% increments to model impact of higher sensitivity associated with the technologies. The EAG also applied the sensitivity shared by the SPIRO-AID study which used ArtiQ.Spiro (see Appendix D4; provided AiC)
Specificity of intervention technology (intervention arm only)	91%, 86%, 81%, 76%	94%, 89%, 84%, 79%	91%, 86%, 81%, 76%	Assumption	Applied 5% decrements to model impact of lower specificity associated with the technologies. The EAG also applied the sensitivity shared by the SPIRO-AID study which used ArtiQ.Spiro (see Appendix D4; provided AiC)
Proportion where spirometry is available (intervention arm only)	38%, 43%, 48%	38%, 43%, 48%	38%, 43%, 48%	Assumption	The EAG also considered accessibility of spirometry separately to the accessibility of objective testing (varied previously).
Proportion where spirometry is done, but the result is unavailable (intervention arm)	10%	10%	10%	Kocks et al. (2023)	Potentially applicable to NuvoAir only; assuming the rest can repeat the measurement in clinic (adding negligible extra time and therefore little cost impact). The study by Kocks et al. included spirometry-naive and those with previous experience of spirometry; which may impact the proportion who can provide acceptable spirometry measurements at home.
Increased sensitivity of alternative test (if spirometry unavailable)	25%	60%	N/A (set to 1 to omit branch)	Assumption: absolute increase of 10%	This will model the few patients requiring “further diagnostic testing” (see Figure 2) which may incur a high cost (majority occurring in hospital setting).
Transition from undiagnosed waiting to undiagnosed treated	0%, 50%	0%, 50%	0%, 50%	NG245. Expert opinion (Appendix B3).	0% scenario is reflective of NICE guidance in asthma (NG245, 2024; section 1.1.2 which states: “Do not confirm a diagnosis of asthma without a suggestive clinical history and a supporting objective test. Code as suspected asthma until the diagnosis is confirmed. [NICE 2017, amended BTS/NICE/SIGN 2024]”). 50% scenario considers “trial of treatment” approach where diagnosis may be based on response to treatment which occurs in NHS practice (Appendix D1).
Level of asthma control	Controlled: 33% Partially controlled: 33% Uncontrolled: 33%	Same as asthma adults	GOLD 1 = Controlled 19.3% GOLD 2 = Partially controlled 55.6% GOLD 3/4 = Uncontrolled 25.1%	Asthma: Assumption COPD: NG115 (2018) Lambe et al. 2019	The EAG considered that patient characteristics may vary by population and setting in which these technologies are used. This sensitivity analysis aims to determine the impact of having an equal proportion of patients across the levels of control appropriate for asthma. COPD: The EAG also considered a sensitivity analysis which modelled 3 COPD severity states (GOLD 1 as well controlled, GOLD 2 as partially controlled, and GOLD 3 and 4 combined into a single uncontrolled state which the EAG felt appropriate due to the low proportion of patients within a GOLD 4 stage, approximately 1.5%). This was operationalised using the starting proportions, exacerbation rates and utilities outlined in NG115 by GOLD stage and the transition probabilities between those stages as

Parameter	Adults (asthma)	Paediatric (asthma)	Adults (COPD)	Source	Comment
					outlined in the economic evaluation by Lambe et al. 2019. The EAG note that the economic model applied a simplification of the modelling approach applied by NG115 which utilised time dependent transition probabilities between different GOLD stages of disease.
Transitions between controlled and uncontrolled	5, 10%	5, 10%	5, 10%	Assumption	The EAG considered that patient characteristics may vary by population and setting in which these technologies are used. The level of control has been varied for a starting cohort; however, this sensitivity analysis enables increased transitions to an uncontrolled state during management which may be applicable to some populations.
Proportion transitioning between “No disease but treated” and “No Disease”	25%	25%	25%	Assumption	Enables modelling of third value proposition that misdiagnoses may be caught and medications withdrawn from patients (where they would not see the clinical benefit). When this has been varied the utility decrement associated with misdiagnosis (that is false positive) was also increased (to 0.01).
Time spent in exacerbation state	6 weeks	6 weeks	6 weeks	Assumption	Increasing the duration that a patient can stay in this state to determine impact on QALY and cost over time horizon.
Exacerbation: underlying hazard in the controlled state	0.39	0.35	0.2337	Assumption (double that of the base case)	The EAG have explored the impact of two changes relating to exacerbation rates. The first here is changing the underlying hazard of exacerbation in the controlled arm (for which 2.5% increase in the partial control and 5% increase in the uncontrolled arm would occur).
Exacerbation: the proportion increases in partial and uncontrolled (from controlled)	Partial control: 5% increase Uncontrolled: 10% increase	Partial control: 5% increase Uncontrolled: 10% increase	Partial control: 5% increase Uncontrolled: 10% increase	Assumption	The EAG have explored the impact of two changes relating to exacerbation rates. The second here is changing the proportion increases in the exacerbation assumed for partial control and uncontrolled states as a relative increase from the controlled state, increasing the exacerbation rate to model a population which may have severe disease.
Cost of further testing	£24.32	£24.32	£24.32	NG245 (2024)	Applied the cost of FeNO (£22.21) and the EAG inflated to 2024 prices.
Price per patient technology (intervention arm only)	£33.86 (ArtiQ) £35.26 (GoSpiro), £163.48 (NuvoAir with device/internet), £151.38 (NuvoAir without device/internet)	£33.86 (ArtiQ) £35.26 (GoSpiro), £163.48 (NuvoAir with device/internet), £151.38 (NuvoAir without device/internet)	£33.86 (ArtiQ) £35.26 (GoSpiro), £163.48 (NuvoAir with device/internet), £151.38 (NuvoAir without device/internet)	Range of technology costs (see Section 6.2.4)	This analysis changes only the cost per patient (assumes diagnostic and clinical performance of all the devices is equivalent). Due to the lack of data available (no head-to-head comparisons), the validity of assumed equivalent performance across the included technologies is currently unknown.
Monitoring costs per patient, relative increase	25%, 50%, 100%	25%, 50%, 100%	25%, 50%, 100%	Assumption	This sensitivity analysis models change in setting of monitoring (which may include outpatient clinical rather than in a primary care setting).
Cost of exacerbation	50%, 100% higher	50%, 100% higher	50%, 100% higher	Assumption	This sensitivity analysis models change in the proportion of exacerbations managed in hospital (an indirectly could be used to model the impact of higher severity exacerbations).
FP diagnosis utility decrement	0.01, 0.02	0.01, 0.02	0.01, 0.02	Li et al. 2019	Systematic review by Li et al. 2019 reported disutilities over 12 months in patients receiving false positive results in breast cancer screening of between 0 and 0.26. The EAG assumes a false positive diagnosis of asthma or COPD will not have a greater impact on utility than a false positive diagnosis of cancer. Therefore, the upper value applied in sensitivity analysis for each monthly cycle is calculated as 0.26 / 12 = 0.0216, rounded to 0.02. Values in the lower end were incorporated into sensitivity analysis but only applied in the model for scenarios where the specificity was different between comparator and intervention arms.

Abbreviations: AiC, Academic in Confidence; COPD, chronic obstructive pulmonary disease; EAG, External Assessment Group; FeNO, Fractional exhaled Nitric Oxide; FP, false positives; GOLD, Global Initiative for Chronic Obstructive Lung Disease; NG, NICE Guidelines; QALY, Quality Adjusted Life Year

6.3 Results from the economic modelling

6.3.1 Asthma (adults)

6.3.1.1 Base case: Increased diagnostic sensitivity

The base case assumed that the intervention arm had a 10% increase in diagnostic sensitivity (when compared with standard care). This resulted in two more true positive cases being identified (Table 33 and Appendix B3).

The intervention was associated with an incremental cost of £5.41 per patient (intervention: £598.70; comparator: £593.30) and 0.0004393 incremental QALYs gain (intervention: 6.829; comparator: 6.829), resulting in an ICER of £12,307/QALY (Table 33). Over the 10-year time horizon, approximately 34% of the total costs (in comparator and intervention arms) were accrued in the diagnostic testing phase; with the remaining 66% of total costs attributed to the treatment and exacerbation costs. The base case assumed the same rate of objective testing across both intervention and comparator arms. Therefore, the number of patients within the “undiagnosed” states awaiting testing is the same in both arms of the model.

6.3.1.2 Base case: Faster access to objective testing

The base case analysis took a starting population of 1,000 patients with suspected asthma, which assumed a higher proportion receive objective testing in the same time frame (intervention: 70% tested within 6 months; comparator: 63.2% tested within 6 months). The intervention identified two more true positives (correct diagnoses) and one more true negative. The intervention arm was also associated with an incremental cost of £11.50 per patient, which was double that observed in the analysis reported in section 6.3.1.1 (a value proposition of 10% increased diagnostic sensitivity), and incremental QALYs were 6 times higher at 0.002771, resulting in an ICER of £4,152/QALY (Appendix B4). The economic model assumed small reductions in staff time required for interpretation (for example reducing from 10 minutes in standard care to 5 minutes for ArtiQ.Spiro, MIR Spiro, EasyOne Connect,

GoSpiro technologies), but this may not free up enough time to increase patient testing capacity in a primary or community care setting. The EAG acknowledges that there may be other ways to increase testing capacity and therefore offer faster access to testing. For example, by having spirometry performed by staff on lower pay bands, as noted in Hayes et al. (2025b). However, because this may not be in line with the Final Scope, and requirement for those performing spirometry to be certified and registered with the ARTP, the EAG has not modelled this scenario. The EAG note that this value proposition is unlikely to be applicable to LungHealth, which is a computer-guided consultation that relies upon prior spirometry measurements; therefore, measurement time is still required, along with approximately 20 to 30 additional minutes to complete a questionnaire with the patient.

NuvoAir is a remote service which delivers a spirometer to the patient, enabling repeated measurements over a time period. The Experts stated however that home measurement would be appropriate for only a small proportion of patients who are familiar with conducting the measurement unassisted (Appendix D3). The clinical evidence also reported that approximately 10% (including those with a diagnosis of asthma or COPD, whom the EAG assume are not spirometry-naive) did not complete the home spirometry session when using NuvoAir; therefore would incur the high technology cost but would not gain health benefit and would likely require referral to standard care, which would increase the ICER. However, because it is used at home, and needs no additional appointment time in the clinic, this technology has the potential to improve the throughput of patients for spirometry by diverting some to home-testing.

The remainder of the technologies may reduce interpretation time but cannot replace clinical oversight and interpretation, which was a view shared by 9 participants undergoing spirometry in primary care (using ArtiQ.Spiro) summarised in the abstract by Doe et al. (2025b). Furthermore, the regulatory approvals for all technologies require that a clinician confirms the diagnosis.

Table 33: Economic results (Asthma – adults)

Scenario	Description	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental Net Monetary Benefit (£)
Value proposition 1 (higher diagnostic accuracy)	Comparator with 37% sensitivity	593.30	6.829	N/A	N/A	N/A	N/A
	Intervention with 47% sensitivity	598.70	6.829	5.41	0.0004393	12,307	3.4
Different sensitivity	Intervention with 42% sensitivity (comparator + 5%)	600.20	6.829	6.87	0.0002196	31,284	-2.5
Different sensitivity	Intervention with 77% sensitivity (comparator + 40%)	590.00	6.83	-3.38	0.001757	Dominant	38.5
Different specificity	Intervention with 86% specificity (comparator - 5%)	602.90	6.829	9.58	0.0004393	21,807	-0.8
Decreased technology costs	Intervention with ArtiQ costs	589.30	6.829	-4.01	0.0004393	Dominant	12.8
Decreased technology costs	Intervention with GoSpiro costs	589.80	6.829	-3.56	0.0004393	Dominant	12.4
Increased technology costs	Intervention with NuvoAir costs (removal of internet costs)	626.70	6.829	33.37	0.0004393	75,970	-24.6
Detection of misdiagnoses	Intervention with 5% of false positives (on treated) detected as not having disease	591.00	6.825	-2.30	0.001466	Dominant	31.6
Time horizon decreased: 2 years	Comparator with 2-year time horizon	261.70	1.567	N/A	N/A	N/A	N/A
	Intervention with 2-year time horizon	266.40	1.567	4.73	8.861e-05	53,352	-3.0
Prevalence decreased to 36%	Comparator with 36 % prevalence	488.10	7.136	N/A	N/A	N/A	N/A
	Intervention with 36% prevalence	494.70	7.137	6.60	0.0002697	24,460	-1.2
Prevalence increased to 80%	Comparator with 80 % prevalence	688.40	6.551	N/A	N/A	N/A	N/A
	Intervention with 80% prevalence	692.70	6.552	4.34	0.0005924	7,319	7.5
Cost of ‘further testing’ reduced	Comparator with lower cost of further testing	451.40	6.829	N/A	N/A	N/A	N/A
	Intervention with lower cost of further testing	460.00	6.829	8.64	0.0004393	19,665	-0.1
Diagnostic accuracy for ArtiQ.Spiro applied from SPIRO AID study [AiC]	Comparator with SPIRO AID sens/spec [AiC]	[redacted]	[redacted]	N/A	N/A	N/A	N/A
	Intervention with SPIRO AID sens/spec [AiC]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Value proposition 2 (increased rate of access to objective testing)	Comparator with 63.2% tested in 6 months	593.30	6.829	N/A	N/A	N/A	N/A
	Intervention with 70% tested in 6 months	604.80	6.831	11.50	0.002771	4,152	43.9

Abbreviations: AiC, academic in confidence; ICER, incremental cost-effectiveness ratio; N/A, not applicable; QALY, quality-adjusted life years

6.3.1.3 Sensitivity analysis

For the rest of the sensitivity analyses the EAG assumed that the diagnostic sensitivity of the intervention was 10% higher than standard care, unless otherwise stated. The adult asthma model was most sensitive to univariate changes in the diagnostic accuracy of the intervention, technology costs per patient, initial prevalence of disease, time horizon, costs of further testing (if spirometry or the alternative, peak flow, are negative) – with each having the potential to increase the ICER above £20,000/QALY. However, the EAG note that the variance in incremental NMB was small, and therefore any future research should be proportionate to its value.

- **Diagnostic accuracy**: Increasing sensitivity of the technologies resulted in higher cost savings because it reduced the need for further testing. Further testing incurs a higher cost because of the likelihood of referral to secondary care when spirometry (or the alternative, peak flow) provides a negative result (see decision tree in Figure 2). At a fixed specificity, the diagnostic sensitivity would have to be at least 9% higher in the intervention arm (intervention: 46%, comparator: 37%) for the intervention to have an ICER below £20,000/QALY. If the intervention had a diagnostic sensitivity of 67% or higher, then it was considered dominant because of the reduced costs. Assuming a fixed sensitivity, decreasing specificity of the technologies below 88% (from 96% in the base case), resulted in an ICER over £20,000/QALY. The EAG note that the results from SPIRO-AID, which were submitted academic-in-confidence, [redacted] However, a lack of diagnostic accuracy evidence meant the EAG was unable to comment on the plausibility of these sensitivity and specificity thresholds for the other technologies listed in the scope.

- **Technology costs**: When the costs of ArtiQ.Spiro and GoSpiro were applied, the interventions were considered dominant because the incremental cost savings were £4.01 and £3.56 per patient respectively. At stakeholder consultation ArtiQ.Spiro stated that integration costs were not applicable. The EAG note that if the £2.38 integration costs were removed for ArtiQ.Spiro technology that the incremental cost savings would increase, and ArtiQ.Spiro would remain dominant. The EAG determined that if technologies had 10% higher diagnostic sensitivity than standard care, a technology cost of £74 per patient (that is, £36.76 more than standard care) would be needed for the ICER to go above £20,000/QALY. For context, this is equivalent 41 minutes of a Band 5 practice nurse.

  When the costs of NuvoAir (the most expensive technology in scope) were applied, the intervention had an incremental cost of £37.22 per patient, and ICER of £84,731/QALY. Removing the mobile phone and internet costs reduced the ICER to £75,970/QALY. Threshold analysis showed that for this technology to achieve an ICER lower than £20,000/QALY one of the following criteria would need to be met:

    - the sensitivity would need to be at least 31% higher (for example, intervention: 68%, comparator: 37%), or
    - the proportion moving into the testing state within 6 months of starting to wait for testing would have to be approximately 5% higher (for example, intervention: 68%; comparator: 63.2%), or
    - the same proportion of patients would need to move into the testing state almost 3 weeks quicker (for example intervention: 63.2% tested with 162 days; comparator: 63.2% tested within 182 days).

  The EAG consider that as NuvoAir delivers the technology directly to the patient and can be used in areas where access to spirometry is lacking or limited, it is plausible that waiting times for testing could be reduced. Costs supplied by NuvoAir cover a 2- to 4-week testing period compared with a

single timepoint test in standard care; therefore, the EAG note that the proportion moving into the testing state two weeks earlier may not result in an earlier diagnosis (as the testing period overlaps with diagnosis). However, if patients move into the testing state beyond one month earlier, this may result in a proportion of patients receiving an earlier diagnosis and achieve an ICER below the willingness to pay threshold. Furthermore, these univariate changes assume all those who are referred to NuvoAir are able to complete testing and does not account for patients who may be unable to complete testing and may incur additional standard care costs. There is a lack of data relating to sensitivity and specificity for this technology, including for the impact of repeated home-based measurements when compared with standard care, and comparative evidence was unavailable for waiting times, therefore future data collection should focus on these outcomes.

As a subset of technology costs attributed per patient, the EAG also conducted scenario analysis which considered measurements conducted by a Band 5 practice nurse (no change from base case) but that interpretation was conducted by a GP (assumed £45 per 10 minutes; Jones et al. 2025). This resulted in the following changes:

- ArtiQ.Spiro and GoSpiro - little impact; technologies still resulted in a cost saving and would be considered dominant (same as base case).
- NuvoAir – where a reduction in the incremental cost per patient was observed however the ICER still exceeded £20,000/QALY (same as base case).
- LungHealth – where a large increase in incremental cost per patient was observed (due to replacing 10 minutes interpretation with a GP in comparator arm with a 20-minute consultation (assumed included interpretation) with a GP). This resulted in the ICER of £38,495/QALY; which is different to the base case.

From this analysis the EAG would note that the economic model is sensitive to per patient costs including the banding and time of staff used to measure and interpret spirometry findings.

- **Prevalence**: The technologies had an ICER greater than £20,000/QALY when the disease prevalence reduced from the 59% used in the base case to 43% or lower. However, the EAG note that changes in this parameter resulted in small changes in incremental NMB.

- **Time horizon**: Larger QALY gains were seen on longer term modelling, because they allow more time for the benefits to accrue and offset initial intervention costs. For example, a 20-year time horizon resulted in a 0.0006245 QALY gain in the intervention arm, whereas the QALY gain was small (0.00008861) when applying a 2-year time horizon, resulting in an ICER of £53,352/QALY. This is a direct consequence of some of the modelled population still being held in "undiagnosed" states while awaiting testing within this short time frame. However, the EAG note that changes in this parameter resulted in small changes in incremental NMB.

- **Cost of further testing:** When the costs of further testing, after a negative spirometry or peak flow result, were reduced to £24.32, the ICER increased to £19,665/QALY. This is unlikely to be a plausible scenario, because this is a lower cost than for an average GP appointment, and further testing for a large proportion of these patients will involve referral to an outpatient or hospital clinic if they are still symptomatic and the suspicion remains that they have asthma.

The model was insensitive to changes in the following parameters: the rate at which patients received objective testing, the proportion of patients receiving "trial of treatment" while waiting for objective testing, the accuracy of alternative tests in the diagnostic pathway, the use of a QALY loss (up to 0.01) for those misdiagnosed with disease, increased monitoring costs for those diagnosed with asthma, increased costs associated with severe exacerbations, and different starting levels of asthma control (Appendix B4).

The economic model developed could also be used to show the impact of the technologies being used in the management phase. For example, if the interventions correctly identified 5% of patients misdiagnosed with asthma (that is, moving them from “no disease, but treated” to “no disease”) this would save £2.30 per patient, making the intervention dominant with an incremental NMB of £11. If a utility decrement was also applied to the false positives while they were receiving inappropriate treatment, the incremental QALYs would increase to 0.001466, and incremental NMB increase to £32. If 2.5% of misdiagnoses were detected, the incremental NMB was £19. The EAG note that using the technologies in this way is outside of the scope for this EVA because the population has been previously diagnosed. However, it demonstrates the flexibility of the economic model to capture a variety of value propositions and supports the potential use of technologies to meet these.

6.3.2 Asthma (children)

6.3.2.1 Base case: Increased diagnostic sensitivity

Results similar to those seen in the adult cohort were observed in children undergoing testing for suspected asthma, over a 10-year time horizon. The incremental cost was £6.87 (intervention: £668.20, comparator: £661.30) and incremental QALYs were 0.001188 (intervention: 7.377, comparator: 7.375), resulting in an ICER of £5,781/QALY and incremental net monetary benefit of £17 (see Table 34 and Appendix B4).

6.3.2.2 Base case: Faster access to objective testing

Assuming a higher proportion receive objective testing in the same time frame (intervention: 70% tested within 6 months; comparator: 63.2% tested within 6 months), the intervention was associated with an incremental cost of £12.29 (intervention: £673.60, comparator: £661.30), incremental QALYs of 0.002101 (intervention: 7.377, comparator: 7.375), resulting in an ICER of £5,849/QALY and incremental net monetary benefit of £30 (see Table 34 and Appendix B4).

Table 34: Economic results (Asthma – children)

Scenario	Description	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Value proposition 1 (higher diagnostic accuracy)	Comparator with 68% sensitivity	661.30	7.375	N/A	N/A	N/A	N/A
	Intervention with 78% sensitivity	668.20	7.377	6.87	0.001188	5,781	16.90
Decreased technology costs	Intervention with ArtiQ costs	658.70	7.377	-2.57	0.001188	Dominant	26.30
Decreased technology costs	Intervention with GoSpiro costs	659.20	7.377	-2.12	0.001188	Dominant	25.90
Increased technology costs	Intervention with NuvoAir costs (removal of internet costs)	696.20	7.377	34.89	0.001188	32,627	-15.00
Time horizon decreased: 2 years	Comparator with 2-year time horizon	228.40	1.675	N/A	N/A	N/A	N/A
	Intervention with 2-year time horizon	233.50	1.675	5.04	0.0002315	21,768	-0.40
Prevalence decreased to 20%	Comparator with 20% prevalence	512.20	7.684	N/A	N/A	N/A	N/A
	Intervention with 20% prevalence	520.20	7.685	7.94	0.0004063	19,531	0.20
Value proposition 2 (increased rate of access to objective testing)	Comparator with 63.2% tested in 6 months	661.30	7.375	N/A	N/A	N/A	N/A
	Intervention with 70% tested in 6 months	673.60	7.377	12.29	0.002101	5,849	29.70

Abbreviations: ICER, incremental cost-effectiveness ratio; N/A, not applicable; NMB, net monetary benefit; QALY, quality-adjusted life years

6.3.2.3 Sensitivity analysis

Similar observations were made as in the asthma (adult) cohort. The model was sensitive to changes in diagnostic accuracy (sensitivity and specificity), technology cost per patient, time horizon and disease prevalence:

- **Diagnostic accuracy**: When the diagnostic sensitivity was only 5% greater for the technology (intervention: 73%; comparator: 68%) the ICER was less than £20,000/QALY. This is because fewer patients need further testing, likely in a secondary care setting, where costs are higher. Increasing the diagnostic specificity of the technology above 88% (intervention: 88%; comparator: 76%) resulted in the intervention being dominant.

- **Technology costs**: When the costs of ArtiQ.Spiro and GoSpiro were applied, the incremental cost savings of £2.57 and £2.12 respectively per patient made the intervention dominant. When used in a paediatric population, if a 10% higher diagnostic sensitivity was assumed, a cost of £117 per patient resulted in ICERs over £20,000/QALY.

  Using the costs of NuvoAir in the intervention arm (with or without additional mobile device and internet costs), the ICER was more than £20,000/QALY. For this technology to achieve an ICER lower than £20,000/QALY, one of the following criteria would need to be met:

    - The sensitivity would need to be at least 15% higher (for example intervention: 83%, comparator: 68%), or

    - The proportion moving to testing within 6 months of beginning to wait for objective testing would need to be 7% greater (for example intervention: 70%; comparator: 63.2%), or

    - The same proportion would need to move to objective testing approximately 1 month quicker (for example intervention: 63.2% tested with 152 days; comparator: 63.2% tested within 182 days).

As within the adult population, the EAG consider it plausible that access to spirometry testing may be faster when using NuvoAir, although consideration should be given for the testing period duration and the proportion who are unable to complete home-based spirometry testing. The EAG reiterate that there is a lack of data available for waiting times and diagnostic accuracy for this technology.

Similarly to the scenario analysis conducted in adults, by assuming interpretation was conducted by a GP; ArtiQ.Spiro and GoSpiro remained dominant, NuvoAir still had an ICER greater than £20,000/QALY. However, in children the increase in incremental costs per patient associated with GP interpretation did not result in an ICER greater than £20,000/QALY (ICER of £15,488/QALY). From this analysis the EAG would note that the economic model is sensitive to per patient costs including the banding and time of staff used to measure and interpret spirometry findings which may differ by population (as evidenced by the different findings between adults and children with suspected asthma).

- **Time horizon:** The shorter time horizon of 2 years resulted in incremental costs of £5.04 per patient, reduced QALYs (0.0002315) and therefore gave an ICER of £21,766/QALY. As also seen in the adult population, this is because not all patients are tested within the shorter time horizon because it takes approximately 6 years for all patients to leave the undiagnosed states (and approximately 2 years for 99% to leave). Therefore, they do not accrue enough of the benefits of treatment to offset the testing costs.

- **Prevalence**: An ICER greater than £20,000/QALY was observed when the disease prevalence was reduced from 59% in the base case, to 19% or lower. Because these technologies would be used in symptomatic patients with clinical history that suggests they have asthma, the EAG considered this threshold unlikely. However, prevalence is an important consideration when considering eligible patients and setting of recruitment.

Overall, there was limited evidence in a paediatric population to support the economic modelling. This included limited data on the prevalence, the proportion

receiving treatment before objective testing, the proportion undergoing objective testing in a given time period, the proportion having spirometry in a primary care or community setting, and diagnostic performance in an exclusively paediatric population. The EAG would highlight that the ages at which the devices can be used varies by technology, and therefore this should be considered in future evidence generation recommendations to ensure it aligns with the purposes for which the devices have gained regulatory approval.

6.3.3 COPD

The EAG note that, in general, larger QALY gains were observed in a COPD population than in the asthma populations. This is because larger differences were assumed between utility multipliers applied to levels of symptom control for this disease than for asthma, therefore allowing greater differentiation between the two arms of the model.

6.3.3.1 Base case: Increased diagnostic sensitivity

Increasing the diagnostic sensitivity of the intervention by 10% over a 10-year time horizon, the intervention was associated with an incremental cost of £14.92 (intervention: £802.30; comparator: £787.40) and difference of 0.002498 QALYs (intervention: 6.079; comparator: 6.076), resulting in an ICER of £5,974/QALY (Table 35 and Appendix B4).

6.3.3.2 Base case: Faster access to objective testing

Assuming a higher proportion receive objective testing in the same time frame (intervention: 70% tested within 6 months; comparator: 63.2% tested within 6 months), led to the intervention having an incremental cost of £26.38 (intervention: £813.80, comparator: £787.40), incremental QALY gain of 0.009178 (intervention: 6.086, comparator: 6.076), and an ICER of £2,874/QALY (Table 35 and Appendix B4).

Table 35: Economic results (COPD)

Scenario	Description	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Value proposition 1 (higher diagnostic accuracy)	Comparator with 37% sensitivity	787.40	6.076	N/A	N/A	N/A	N/A
	Intervention with 47% sensitivity	802.30	6.079	14.92	0.002498	5,974	35.00
Different sensitivity	Intervention with 42% sensitivity (comparator + 5%)	807.10	6.078	19.67	0.001249	15,751	5.30
Different sensitivity	Intervention with 67% sensitivity (comparator + 30%)	783.30	6.084	-4.08	0.007493	Dominant	153.90
Different specificity	Intervention with 81% specificity (comparator - 18%)	815.40	6.079	28.02	0.002498	11,216	21.90
Decreased technology costs	Intervention with ArtiQ costs	774.80	6.079	-12.65	0.002498	Dominant	62.60
Decreased technology costs	Intervention with GoSpiro costs	776.10	6.079	-11.34	0.002498	Dominant	61.30
Increased technology costs	Intervention with NuvoAir (no internet) costs	884.30	6.079	96.85	0.002498	38,775	-46.90
Time horizon decreased: 2 years	Comparator with time horizon 2 years	304.30	1.411	N/A	N/A	N/A	N/A
	Intervention with time horizon 2 years	318.20	1.411	13.87	0.0006212	22,320	-1.40
Prevalence decreased to 20%	Comparator with 20% prev	475.90	6.759	N/A	N/A	N/A	N/A
	Intervention with 20% prev	497.90	6.759	21.92	0.0008694	25,216	-4.50
Diagnostic accuracy for ArtiQ.Spiro applied from SPIRO AID study [AiC]	Comparator with SPIRO AID sens/spec [AiC]	[redacted]	[redacted]	N/A	N/A	N/A	N/A
	Intervention with SPIRO AID sens/spec [AiC]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Value proposition 2 (increased rate of access to objective testing)	Comparator with 63.2% tested in 6 months	787.40	6.076	N/A	N/A	N/A	N/A
	Intervention with 70% tested in 6 months	813.80	6.086	26.38	0.009178	2,874	157.20

Abbreviations: AiC, academic in confidence; ICER, incremental cost-effectiveness ratio; N/A, not applicable; NMB, net monetary benefit; QALY, quality-adjusted life years

6.3.3.2 Sensitivity analysis

The COPD model was also sensitive to changes in technology cost per patient and disease prevalence:

- **Diagnostic accuracy**: When the diagnostic sensitivity of the intervention was greater than 64%, the intervention was considered dominant (cost saving). When specificity decreased to 75% (base case 99%), the ICER remained less than £20,000/QALY. The EAG note that when the sensitivity and specificity of ArtiQ.Spiro were applied from the SPIRO-AID study (provided AiC, Appendix D4), [redacted].

  Technology costs per patient: When modelling the costs of ArtiQ.Spiro and GoSpiro, the intervention was considered dominant because of cost savings of £12.65 and £11.34 per patient respectively. If the interventions had diagnostic sensitivity 10% higher than standard care, a cost of £100 per patient would result in ICERs over £20,000/QALY.

  When using the costs of NuvoAir (with or without additional mobile device and internet costs), the ICER was more than £20,000/QALY. For this technology to achieve an ICER lower than £20,000/QALY, one of the following criteria would need to be met:

    - Sensitivity would need to be at least 18% higher (for example, intervention: 55%, comparator: 37%), or
    - The proportion moving into the testing state within 6 months of beginning to wait for treatment would have to be 4% greater (for example, intervention: 67.0%; comparator: 63.2%), or
    - The same proportion should move into the testing state 20 days quicker (for example, intervention: 63.2% tested within 162 days; comparator: 63.2% tested within 182 days).

As with the asthma populations, the EAG consider it plausible that access to spirometry testing may be faster when using NuvoAir, but consideration should be given to the testing period being longer than in standard care, and a proportion of patients who home testing is not suitable for.

By assuming interpretation was conducted by a GP; ArtiQ.Spiro and GoSpiro remained dominant, NuvoAir still had an ICER greater than £20,000/QALY and LungHealth had an ICER of £19,467/QALY. From this analysis the EAG would note that the economic model is sensitive to per patient costs including the banding and time of staff used to measure and interpret spirometry findings which may differ by population.

- **Time horizon**: Over a 2-year time horizon, there were incremental costs of £13.87 per patient, reduced QALYs (0.000621) and an ICER of £22,320/QALY. As with the asthma population, this is because fewer patients are tested over this shorter horizon (where it takes approximately 6 years for all patients to leave the 'undiagnosed' states). Patients therefore do not accrue the utilities needed to offset the increase in costs.

- **Prevalence**: When prevalence of disease was 25% or lower (compared with 59% in the base case), technologies had an ICER greater than £20,000/QALY. Because these technologies would be used in patients with symptoms and clinical history suggesting COPD, the EAG considers this threshold unlikely to be plausible.

The model was not sensitive to changes in costs of monitoring or costs of exacerbation in a COPD population.

6.4 Summary and interpretation of the economic evidence

Results from this modelling work should not be interpreted as evidence or lack of evidence of cost-effectiveness. Instead, this modelling work has highlighted key evidence gaps and key drivers (see Table 36) of differences in costs and utilities of technologies used to support spirometry interpretation when compared with standard care. These should be addressed before completing a full economic evaluation in the future.

Key findings:

- The EAG focused efforts on building a conceptual economic model of the initial diagnosis of lung conditions using the technologies in scope and subsequent management of these lung conditions, encompassing levels of symptom control (asthma) or disease severity (COPD). The conceptual economic model allows exploration of multiple value propositions which was required because of the different functionality of the technologies, and different patient populations and settings they would be used in. The model was used to explore different scenarios in which the technologies in scope might be cost effective when compared with standard care.

- Throughout the modelling, incremental costs and QALYs tended to be very small, and the clinical and economic significance of estimated differences is unclear.

- Key areas where evidence is needed include: diagnostic performance (sensitivity and specificity) in an undiagnosed population. The EAG note that this was missing for all technologies except ArtiQ.Spiro, where RCT data in a UK setting (albeit with a sample size) was available. ArtiQ.Spiro would benefit from a real-world evaluation with a larger sample size to ensure the results from the RCT are generalisable to a real-world context in line with the NICE real-world evidence framework (NICE, 2025). In the conceptual economic model, changes in diagnostic sensitivity and specificity demonstrated a potential for the ICER to exceed £20,000/QALY across adults with suspected asthma or COPD. Changes in these parameters had a lower impact in children with suspected asthma.

- The economic model was also sensitive to the comparatively high per-patient technology costs of NuvoAir, where it resulted in an ICER greater than £20,000/QALY. Better understanding of its cost breakdown and how it may be implemented in an NHS setting may better inform future economic evaluations. The costs associated with two technologies was unknown (MIR Spiro, EasyOne Connect) and therefore not incorporated into the conceptual model.

- The EAG note that the costs of ArtiQ.Spiro and Go Spiro, and potential detection of false positives all reinforced conclusions across all three modelled cohorts and therefore do not warrant further data collection.

- The EAG note that in some modelled scenarios, univariate changes in disease prevalence (all three modelled cohorts) and further test costs (adults with suspected asthma only) could increase the ICER above £20,000/QALY. It is worth considering how these outcomes may vary when implementing the technologies in different settings (such as hospital clinics, or community diagnostic centres).

Table 36: Summary of parameters which the conceptual economic model is sensitive to

	Conceptual economic model parameter sensitivity			
	Insensitive	**Sensitive**	**More-sensitive (<u>not</u> cost-effective)**	**More-sensitive (cost-effective)**
Cohort	Parameter changes associated with ICER <£20,000/QALY	Parameter changes associated with ICER >£20,000/QALY but small changes in incremental NMB (less than £10)	Parameter changes associated with changes in ICER >£20,000/QALY **and** large negative changes in incremental NMB (greater than £10)	Parameter changes resulting in the intervention arm being considered dominant **and** large positive changes in incremental NMB (greater than £10)
Asthma (adult)	• Rate of objective testing; • Spirometry available; • Per-patient technology costs (LungHealth); • Start age; • Long-time horizon (5 years, 20 years); • Alternative testing sensitivity; • Proportion receiving treatment whilst awaiting treatment; • Starting levels of control (controlled, partially controlled, uncontrolled); • Time in exacerbation increased (6 weeks); • Monitoring costs; • Exacerbation costs; • Internal transitions between levels of control; • Exacerbation rate	• Sensitivity (less than 45%); • Short-time horizon (2 years); • Prevalence; • Lower costs of further testing (£24.32)	• Specificity (below 88%); • Per-patient technology costs (NuvoAir)	• Sensitivity (greater than 67%); • Diagnostic accuracy (SPIRO-AID); • Detection of false positive cases; • Per-patient technology costs (ArtiQ, GoSpiro)
Asthma (children)	• Sensitivity (73% or greater) • Rate of objective testing; • Spirometry available; • Per-patient technology costs (LungHealth); • Start age; • Long-time horizon (5 years, 20 years); • Alternative testing sensitivity; • Proportion receiving treatment whilst awaiting treatment; • Starting levels of control (controlled, partially controlled, uncontrolled); • Time in exacerbation increased (6 weeks); • Monitoring costs; • Exacerbation costs; • Internal transitions between levels of control; • Exacerbation rate; • Lower costs of further testing (£24.32)	• Short-time horizon (2 years); • Prevalence	• Per-patient technology costs (NuvoAir)	• Specificity (greater than 88%) • Detection of false positive cases; • Per-patient technology costs (ArtiQ, GoSpiro)
COPD	• Rate of objective testing; • Spirometry available; • Per-patient technology costs (LungHealth); • Start age; • Long-time horizon (5 years, 20 years); • Alternative testing sensitivity; • Proportion receiving treatment whilst awaiting treatment; • Starting levels of control (controlled, partially controlled, uncontrolled); • Time in exacerbation increased (6 weeks); • Monitoring costs; • Exacerbation costs; • Internal transitions between levels of control; • Exacerbation rate; • Specificity; • Lower costs of further testing (£24.32)	• Short-time horizon (2 years); • Prevalence	• Per-patient technology costs (NuvoAir)	• Sensitivity (greater than 64%); • Diagnostic accuracy (SPIRO-AID); • Detection of false positive cases; • Per-patient technology costs (ArtiQ, GoSpiro)

Note threshold values in brackets need to be compared to parameter values applied in the base case.

7. Integration into the NHS

Existing use in the NHS

Of the 6 technologies included in this EVA, 2 companies have not responded to NICE's requests for information. Of the remaining 4, 3 are currently used within the NHS (ArtiQ.Spiro, LungHealth and NuvoAir). A large proportion of the evidence available for these 3 technologies is within a UK NHS setting, however evidence for LungHealth and NuvoAir largely focuses on real-world clinical review of patients with a diagnosis of COPD or asthma rather than their use as part of a diagnostic pathway. In contrast, evidence for ArtiQ.Spiro is focused on spirometry diagnostic and quality assessment accuracy with a range of study designs (Table 3) and captures evidence for most outcomes in scope of this EVA (Table 38).

Implementation considerations

The EAG note that there are some key differences between the technologies that may impact how they integrate into the diagnostic pathway. For example, the 4 technologies that include compatible spirometer hardware (EasyOne Connect, GoSpiro, MIR Spiro, and NuvoAir) may offer home-based spirometry. The oversight of home-based spirometry differs between the technologies, with NuvoAir offering independent clinical review and oversight of the spirometry testing. Implementation of NuvoAir may therefore offer an independent diagnostic pathway for areas where access to spirometry is limited or unavailable or a home assessment is preferred. The EAG note that GoSpiro may be used at home for diagnosis in 2 ways; through sending the technology directly to the patient and using the avatar-guided process to instruct the patient to perform spirometry, or to send the technology with a healthcare professional to the patients' home. This latter model of delivery may also be used for EasyOne Connect or MIR Spiro, which have portable spirometers within their product range.

There is a lack of evidence in using EasyOne Connect, GoSpiro, or MIR Spiro to support diagnosis in a home setting and Experts have advised that this home-based spirometry approach may be applicable to a small proportion of patients (Appendix

D2). Therefore, the EAG have not explicitly modelled this method of service delivery within this EVA. The EAG note that implementation of a technology in home settings, such as when used to inform an initial diagnosis, may require additional resources (such as staff travel time or courier fees). Additionally, the EAG note that spirometry results obtained in the clinical setting by clinical staff may not have the same test accuracy as those done at home by a patient. These factors may influence the clinical- and cost-effectiveness of the technologies.

LungHealth is a software-only technology that offers a computer-guided consultation, part of which includes the analysis of input spirometry test data. Implementation of LungHealth therefore requires an additional appointment with a healthcare professional to go through the consultation process in addition to access to a spirometer and healthcare professional able to instruct and perform spirometry.

ArtiQ.Spiro, as a software only technology, also requires access to a spirometer and a healthcare professional who can provide patient instructions and perform spirometry, however, it does not require any additional time or clinical visits. The technology is integrated with two spirometers which are in common use within the NHS (Table 2) but can be used with other spirometers. There is some real-world UK NHS evidence to suggest that the use of ArtiQ.Spiro can reduce the time taken to interpret spirometry and may release clinical resources (Table 9).

Training requirements

Staff training for using the technologies also differs, lasting between 15 minutes to a full day followed by a mentoring period (Appendix C1). For home-based spirometry using NuvoAir, patients are instructed on the performance of spirometry by NuvoAir representatives during the onboarding process. Three technologies (MIR Spiro, EasyOne Connect and GoSpiro) also provide training to the patients through an avatar (which guides patients through the spirometry manoeuvre with the aim of teaching and improving technique).

Preferences and accessibility considerations

Home-based spirometry may be preferred to clinic-based spirometry for various reasons, such as the ability to perform spirometry when symptomatic or where local spirometry services are limited, unavailable or impractical for a person to attend. However, it is acknowledged that not all patients may be able to achieve valid spirometry tests in a home setting (Table 20) and may require additional testing in standard care to support accurate diagnosis. One Expert noted that existing spirometers give information to identify where a test has not been performed adequately either because of human or technical error, but that this may differ for patient and clinician views. Such as, the patient might not know why their test was not acceptable so they cannot do anything to rectify this. There is also conflicting evidence relating to the comparability of home- and clinic-based spirometry results (Anand 2023; Moor 2020; Turner 2021).

NuvoAir requires a mobile phone and internet access to submit test data (Appendix C1) which may present accessibility considerations for some patients. One Expert reported that the NuvoAir app sometimes fails to connect and so the patient (or clinician) taking the reading thinks they have submitted it, but it has not been recorded in the system.

Sustainability considerations

All technologies require hardware with disposable or reusable consumables to perform spirometry. NuvoAir reported that the spirometer that is sent to the patient can be recycled or returned to the clinical service if requested.

NHS England reported that medicines account for 25% of emissions within the NHS, of which inhalers (3% of emissions) occur at the 'point of use'. They reported that a total of 20% of emissions are primarily found in the manufacturing and freight inherent in the supply chain. Therefore, tools that can help with better use, adherence and management of inhalers could reduce the direct and indirect emissions linked to inhalers and other associated medicines. This could reduce the carbon footprint associated with the management of asthma in line with delivering a net zero NHS. The manufacturers of ArtiQ.Spiro, LungHealth and NuvoAir have provided publicly available Sustainability and Carbon Reduction Action Plans. The

manufacturer of GoSpiro stated that they have a Carbon Reduction Plan, but this was not shared with the EAG at the time of writing.

8. Evidence gap analysis

8.1 Ongoing studies

A total of 10 ongoing studies were identified across 4 manufacturers, Table 37. In addition to this, GoSpiro (Monitored Therapeutics) advised that [redacted] No further information was provided by the Company, and no publicly available ongoing studies were identified by the EAG for that technology.

Table 37: Ongoing studies and their relevance to the decision problem (N=10)

Ongoing study	Alignment with scope	Indicated study end date	EAG comments
ArtiQ.Spiro (2 studies)	-	-	-
AI in PRImary Care Spirometry Pathways for Diagnosis of Lung Disease (APRIL) [NCT05865249]	Population: Full match to scope Intervention: Full match to scope Comparator: Full match to scope Setting: Full match to scope Outcomes: Partial match to scope	Estimated study completion date 01/04/2024.	Original recruitment was estimated as n=150 patients, but actual n=63. Status currently stated as “Active, not recruiting” last verified in January 2024.
Ambition spiromètre, Yvoire (2025) [provided by company]	Population: Partial match to scope. Intervention: Full match to scope Comparator: Full match to scope Setting: Partial match to scope Outcomes: Unable to determine	Estimated study completion date: 30/05/2026.	Number of participants to be recruited and recruitment progress not reported. Non-UK primary care setting. Sponsored by AstraZeneca France
EasyOne (no studies)	-	-	-

Ongoing study	Alignment with scope	Indicated study end date	EAG comments
LungHealth (1 study)	-	-	-
Analysis of the MISSION project data [provided by Company]	Population: Partial match to scope Intervention: Full match to scope Comparator: No match to scope Setting: Full match to scope Outcomes: Partial match to scope	Company report data available in January 2026	Real-world evaluation design, set in Greater Manchester, UK. Review of patients with an existing diagnosis of COPD and asthma.
MIR Spiro (2 studies)	-	-	-
Detection of aspergillus fumigatus and sensitization in COPD patients with bronchiectasis vs without bronchiectasis, [NCT02332122]	Population: Partial match to scope Intervention: Partial match to scope Comparator: No match to scope Setting: Partial match to scope Outcomes: No match to scope	Estimated study completion of 05/2017	Study listed as unknown status, last update 24/08/2015. Use of home spirometer to measure lung function at home in patients diagnosed with COPD.
An international patient-led registry in fibrotic interstitial lung diseases using eHealth technology (I-FILE) [NCT04304898]	Population: Partial match to scope Intervention: Partial match to scope Comparator: Partial match to scope Setting: Partial match to scope Outcomes: Partial match to scope	Estimated study completion of 07/2026	Study status recruiting with last update 20/03/2024. Home spirometry for people with ILD however may report outcomes for accuracy and interpretation of spirometry using technology in scope. Unclear impact of algorithm or software component within study design.
NuvoAir (5 studies)	-	-	-
The COPD CARE study: evaluating the impact of a virtual-first COPD service on major cardiac and respiratory events, [NCT06379529]	Population: Partial match to scope Intervention: No match to scope Comparator: No match to scope	Estimated study completion of 01/12/2027	No reported use of spirometry; NuvoAir clinical remote monitoring only. Last updated 28/05/2025, status listed as not yet recruiting.

Ongoing study	Alignment with scope	Indicated study end date	EAG comments
	Setting: Partial match to scope Outcomes: No match to scope		
Pragmatic assessment of the NuvoAir clinical service in the management of patients with COPD (PROMISE),NCT05955482]	Population: Partial match to scope Intervention: Partial match to scope Comparator: No match to scope Setting: Partial match to scope Outcomes: No match to scope	Estimated study completion of 07/2025	Listed as active, not recruiting with last update 28/05/2025. NuvoAir clinical remote monitoring with weekly spirometry. Interim report available via pre-print server, Harker (2025).
The use of home spirometry in the monitoring of patients with acute exacerbation of asthma [NCT05603494]	Population: Partial match to scope Intervention: Partial match to scope Comparator: No match to scope Setting: Partial match to scope Outcomes: No match to scope	Estimated study completion 30/07/2024	No results identified, unknown status (last update 07/09/2023 listed as recruiting).
Hywel Dda University Health Board Severe asthma service, South Wales, [provided by company]	Population: Full match to scope Intervention: Full match to scope Comparator: No match to scope Setting: Partial match to scope Outcomes: Partial match to scope	Company report that expected results are anticipated in February 2026	Real-world evaluation. Recruitment listed as ongoing (n=49), target recruitment not reported. EAG unable to verify any study details. Patients without a lung condition diagnosis however unclear of any primary care involvement.
University College London Hospital asthma service, [provided by company]	Population: Full match to scope Intervention: Full match to scope Comparator: No match to scope Setting: Partial match to scope Outcomes: Partial match to scope	Company report that expected results are anticipated in February 2026	Real-world evaluation. Recruitment listed as ongoing (n=34), target recruitment not reported. EAG unable to verify any study details. Patients without a lung condition diagnosis however unclear of any primary care involvement.

Abbreviations: COPD, chronic obstructive pulmonary disease; EAG, External Assessment Group

8.2 Evidence gap analysis

The EAG has summarised the evidence gaps across the technologies included in this EVA against the outcomes listed in the Final Scope, Table 38. The EAG note that none of the ongoing studies identified in Table 37 fully address the evidence gaps or scope of the decision problem. The EAG note that the APRIL [NCT05865249] trial for ArtiQ.Spiro, may capture data relating to health-related quality of life and healthcare resource use, however as a feasibility trial for an RCT, it is unclear whether the data would be precise or reliable enough for comparative analysis and whether any data would be generalisable to a real-world setting.

Table 38: Evidence gap analysis

Key: **AMBER**, some evidence available; **GREEN**, evidence available; **RED**, no evidence available

Outcomes	ArtiQ.Spiro (Clario)	EasyOne Connect (NDD)	GoSpiro (Monitored Therapeutics)	LungHealth (LungHealth)	MIR Spiro (MIR)	NuvoAir (NuvoAir)
Diagnostic accuracy of initial diagnosis	**GREEN**	**RED**	**RED**	**AMBER** (no comparative evidence, largely in a diagnosed population)	**AMBER** (single non-UK study using assumed older model of technology)	**AMBER** (no comparative evidence, largely in a diagnosed population)
Accuracy of interpretation of spirometry	**AMBER** (single study)	**RED**	**RED**	**AMBER** (no comparative evidence)	**AMBER** (no comparative evidence)	**RED**
Quality of spirometry performance	**GREEN**	**RED**	**RED**	**RED**	**RED**	**AMBER** (no comparative evidence, largely in a diagnosed population)
Access to spirometry and the number of tests performed	**AMBER** (single abstract)	**RED**	**RED**	**RED**	**RED**	**AMBER** (no comparative evidence, largely in a diagnosed population)
Time to perform and interpret spirometry	**GREEN**	**RED**	**RED**	**AMBER** (no comparative evidence)	**AMBER** (no comparative evidence)	**RED**
Time-to-diagnosis	**AMBER** (single study, no prospective evidence)	**RED**	**RED**	**RED**	**RED**	**RED**
Number of referrals to secondary care for a diagnosis to be made	**RED**	**RED**	**RED**	**RED**	**RED**	**AMBER** (no comparative evidence, largely in a diagnosed population)
Number of hospital admissions due to exacerbations because of missed diagnosis and/or treatment	**RED**	**RED**	**RED**	**RED**	**RED**	**RED**
Mortality	**RED**	**RED**	**RED**	**RED**	**RED**	**RED**
Morbidity	**RED**	**RED**	**RED**	**RED**	**RED**	**RED**
Clinician confidence in performing quality-controlled diagnostic spirometry, interpreting results and making a diagnosis in primary care/CDCs	**GREEN**	**RED**	**RED**	**RED**	**RED**	**AMBER** (single study)
Clinician acceptability, perceived ease of use, experience and satisfaction	**GREEN**	**RED**	**RED**	**AMBER** (single study)	**AMBER** (single study)	**AMBER** (single study)
Health-related quality of life (EQ-5D-3L)	**RED**	**RED**	**RED**	**RED**	**RED**	**RED**
Patient and carer acceptability, views, experience and satisfaction	**AMBER** (single study)	**RED**	**AMBER** (single study)	**RED**	**AMBER** (evidence relating to spirometer only, in diagnosed populations)	**AMBER** (evidence largely in diagnosed populations)
Staff time and cost at different specialisms and levels of pay	**AMBER** (1 poster and 1 editorial considered within the clinical evidence with limited details captured relating to time to perform and interpret and staff banding in service redesign)	**RED**	**RED**	**RED**	**RED**	**RED**
Health service resource use at different settings	**AMBER** (1 poster and 1 editorial considered within the clinical evidence with limited details captured relating to time to perform and interpret and staff banding in service redesign)	**RED**	**RED**	**RED**	**RED**	**RED**

The EAG note some clinical evidence gaps for the technologies relating to the decision problem for this early value assessment:

Population gaps:

- Evidence exclusively in an undiagnosed population was only available for ArtiQ.Spiro, MIR Spiro and NuvoAir.
- LungHealth, NuvoAir and ArtiQ.Spiro had evidence in a mixed population (those with and without a diagnosis of asthma, COPD, or ILD).
- Evidence in scope for GoSpiro was only available in people with a diagnosis of COPD.
- Evidence in people with suspected or confirmed ILD was only available for ArtiQ.Spiro.
- There is limited evidence in a paediatric population, however, future evidence should consider the different lower age limits stated across the technologies in their indications for use.

Intervention gaps:

- No published evidence in scope for EasyOne Connect, limited published evidence available for GoSpiro (1 publication) and MIR Spiro (1 publication, 1 pre-print publication, 1 abstract).
- Evidence for the use of NuvoAir and LungHealth was largely relating to their use for monitoring or clinical review of COPD or asthma.
- General lack of transparent reporting of the software name, version and associated hardware used.

Comparator gaps:

- Lack of comparative evidence across most of the technologies to show the impact of using the technologies to support diagnostic pathways, including the

accuracy of the algorithm for spirometry quality assessment and interpretation compared with a reference standard.

- Lack of comparative evidence to show impact of implementation of the technologies on waiting times, staffing and resources.

Outcome gaps:

- Lack of diagnostic accuracy (sensitivity and specificity) data for all but one technology in scope.
- Lack of longitudinal outcomes, including mortality, morbidity, time-to-diagnosis, staff time and resource use, number of secondary care referrals for diagnosis and hospital admissions because of missed diagnosis or treatment.

Other considerations:

- General lack of peer-reviewed evidence for most technologies.
- UK NHS and real-world evidence was available for three technologies (ArtiQ.Spiro, LungHealth, NuvoAir).
- UK RCT evidence is available for one technology in scope (ArtiQ.Spiro) that aligns well with the scope of this EVA. The RCT was small, and the author stated that real-world evaluation of effectiveness is required. For the remaining technologies, it may be difficult to emulate this study design and outcomes through collection of real-world evidence. Potential confounders, such as level of clinician experience or baseline population differences, may need to be accounted for when considering future study methods.
- Conceptual economic modelling has shown that the model is most sensitive to sensitivity and specificity and technology costs (including staff band and time used to measure and interpret spirometry in the comparator and with each of the technologies) and that small differences in long-term outcomes may not significantly impact the overall cost-effectiveness of the technologies.

Therefore, the value of requesting longer-term outcomes in future data collection should be carefully considered.

- Two technologies included in this EVA may be used for patient monitoring, either during clinical reviews (LungHealth) or through remote patient monitoring with physiologist oversight (NuvoAir). While the use of technologies for monitoring is out of scope for this assessment, the EAG acknowledges that these technologies may be able to opportunistically identify people who have been incorrectly diagnosed with asthma or COPD. For technologies with a value proposition for supporting identifying patients with a false positive diagnosis, data should be captured to determine the proportion of patients identified and impact on health resource outcomes, such as changes in medications, onward referrals and quality of life.

- NuvoAir has provided costs for a 2-to-4-week diagnostic assessment period although evidence considered by the EAG included a home testing period up to 12 weeks. The EAG note that some key outcomes may differ depending on the length of the diagnostic assessment period, for example diagnostic accuracy over a test period of 12 weeks may not be generalisable to a testing period of 2 weeks. Similarly, the length of the testing period may directly impact time-to-diagnosis. Therefore, data collection should reflect the intended implementation within the NHS to ensure generalisability.

- The costs of EasyOne Connect and MIR Spiro are currently unknown.

8.3 Key areas for evidence generation

The EAG have considered priorities for future evidence generation based on clinical evidence gaps and the results of the conceptual economic model combined. The EAG have suggested recommendations for research questions and study designs for the technologies in scope of this assessment, Table 39.

- Five technologies (EasyOne Connect, GoSpiro, LungHealth, MIR Spiro, NuvoAir) should capture data for accuracy of quality assessment and interpretation (when compared with standard care) in an undiagnosed population. Univariate economic modelling ([redacted]) suggests that it is plausible that ArtiQ.Spiro could be cost-effective when used to support diagnosis of lung conditions in primary care. This diagnostic accuracy evidence (in an undiagnosed population) is lacking across the other technologies in scope. Because of differences in functionality and implementation requirements between technologies, and lack of data comparing the technologies against each other, the EAG cannot assume clinical equivalence of the other technologies to ArtiQ.Spiro. The setting of future studies should be explicitly reported as this may impact the disease prevalence and cost of subsequent testing which may impact economic outcomes. Studies should also report results from suspected asthma, COPD and ILD populations separately because cost drivers identified were different between these populations.

- ArtiQ.Spiro may benefit from further evidence collection to ensure generalisability of the RCT results in a larger population in a real-world NHS context.

- Per-patient technology costs should be determined for two technologies; MIR Spiro and EasyOne Connect which are currently unknown. Similarly, better understanding of the implementation costs associated with implementing NuvoAir in a home setting (including uptake, drop out, and replacement of NHS time in measurement and interpretation which contribute to per patient technology costs), will support future economic modelling.

Table 39: Evidence generation recommendations

#	Research question	Technologies	Recommended study design	Outcomes
1.	What is the current sensitivity and specificity for diagnosing lung conditions (including asthma, COPD or ILD) when used within a primary or community care setting compared with standard care against a reference standard of a respiratory expert?	EasyOne Connect, GoSpiro, LungHealth, MIR Spiro, NuvoAir ArtiQ.Spiro may benefit from data in a larger population in a real-world context	Diagnostic accuracy (retrospective review of clinical case dataset)	Diagnostic accuracy, quality of spirometry performance, accuracy of interpretation of spirometry results.
2.	What is the cost per patient of implementing the technologies in the primary or community care diagnostic pathway (for asthma, COPD, ILD)?	MIR Spiro, EasyOne Connect	Before-and-after study (service evaluation)	Waiting time including time-to-diagnosis, staff time and cost at different specialisms, time to perform and interpret spirometry, quality of spirometry performance, number of referrals to secondary care for referrals to be made, clinician and patient acceptability and ease of use.
3.	What is the proportion of patients or patient characteristics of people who can perform remotely instructed home-based spirometry to inform a clinical diagnosis of asthma, COPD or ILD?	NuvoAir	Prospective cohort (service evaluation)	Quality of spirometry performance, number of referrals to secondary care for a diagnosis to be made, patient and carer acceptability, views and satisfaction.

Abbreviations: COPD, chronic obstructive pulmonary disease; EAG, External Assessment Group ; ILD, interstitial lung disease

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10. Appendices

Appendix A - Literature searching

Appendix A1: Search strategies

Economics searches

Initial testing suggested limited relevance of results mentioning product names (as found in the clinical evidence search). However, searching more broadly (anything relating to diagnosis and treatment of lung disease) risked returning an unmanageable number of results. The economic aspect of the search was made relatively specific using terms based on the CADTH narrow economic filter (expanded slightly), instead of a broader filter.

Database/Source	Platform/URL	Date range	Date searched	Retrieved Results
MEDLINE(R) and In-Process, In-Data-Review & Other Non-Indexed Citations (with adapted specific economic search filter)	OVID	1946 to 29/8/2025	1/9/2025	133
Embase (with adapted specific economic search filter)	OVID	1974 to 28/8/2025	1/9/2025	206
NHS EED (via CRD Database website)	From inception up to and including 31 December 2014, when active updating of these databases ended.	Up to date	1/9/2025	33
International HTA Database	https://database.inahta.org/	Up to date	1/9/2025	3
RePEc IDEAS	https://ideas.repec.org/	Up to date	1/9/2025	7
PEDE (Paediatric Economic Database	http://pede.ccb.sickkids.ca/pede/	Up to date	1/9/2025	11

Evaluation project database)				
CEA Registry (the Tufts Medical Center Cost-Effectiveness Analysis Registry)	https://cear.tuftsmedicalcenter.org/	Up to date	1/9/2025	3

Total number of records retrieved from all sources: 396
Total number of records after deduplication: 315

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to August 29, 2025>

1	exp *Asthma/ or *lung diseases, obstructive/ or exp *pulmonary disease, chronic obstructive/ or exp *Lung Diseases, Interstitial/ or exp *Pulmonary Fibrosis/ or *respiratory tract diseases/ or *lung diseases/ or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ti. or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ab. /freq=3	379058
2	((asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).kf. or (exp Asthma/ or lung diseases, obstructive/ or exp pulmonary disease, chronic obstructive/ or exp Lung Diseases, Interstitial/ or exp Pulmonary Fibrosis/ or respiratory tract diseases/ or lung diseases/)) and (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis or ((lung or pulmonary or respiratory) adj3 disease*)).ab.	201639
3	1 or 2	398962
4	di.fs. or (diagnos* or detect*).ti. or (diagnos*.kf. and diagnos*.ab.) or diagnos*.ab. /freq=3	4123086
5	spiro*.mp. or (pulmonary function or lung function).ti,hw,kf. or (pulmonary function or lung function).ab. /freq=2	119885
6	(algorith* or AI or artificial intelligen* or machine learning or large language or natural language or deep learning or rule based or rules based).ti,kf. or *medical informatics applications/ or *decision making, computer-assisted/ or *diagnosis, computer-assisted/ or exp *decision support techniques/ or *decision support systems, clinical/ or *decision tree/ or exp *algorithms/ or exp *software/ or ((interpret* or decision*) adj3 (guided or support*)).mp.	605329
7	(4 and 5) or (4 and 6) or (5 and 6)	131132
8	3 and 7	12698
9	*Economics/	10826
10	exp *Health Care Costs/	33759
11	(economic adj2 model*).mp.	16543
12	(cost minimi* or cost-utilit* or health utilit* or economic evaluation* or economic review* or cost outcome* or cost analys?s or economic analys?s or budget* impact analys?s).ti,ab,kf.	49957

13	(life year or life years or qaly* or cost-benefit analys?s or cost-effectiveness analys?s).ab,kf.	48375
14	exp *"costs and cost analysis"/ or exp *economics, hospital/ or exp *economics, medical/	101917
15	*Budgets/	4916
16	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab. /freq=3	35292
17	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed or budget*).ti,kf.	326386
18	or/9-17	404353
19	8 and 18	133

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=77IxT0dH6RwdamtUsvJT4wNQbOE2DZeDnMZeiwdUCJ8I2vMvM4p0CE773ZJbI5ATU

Embase <1974 to 2025 August 28>

1	exp *asthma/ or *chronic obstructive lung disease/ or *obstructive lung disease/ or exp *interstitial lung disease/ or *lung disease/ or *respiratory tract disease/ or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ti. or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ab. /freq=3	473838
2	((asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).kf. or (exp asthma/ or chronic obstructive lung disease/ or obstructive lung disease/ or exp interstitial lung disease/ or fibrosing alveolitis/ or lung disease/ or respiratory tract disease/)) and (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis or ((lung or pulmonary or respiratory) adj3 disease*)).ab.	439296
3	1 or 2	609729
4	di.fs. or (diagnos* or detect*).ti. or (diagnos*.kf. and diagnos*.ab.) or diagnos*.ab. /freq=3	5296997
5	spiro*.mp. or (pulmonary function or lung function).ti,hw,kf. or (pulmonary function or lung function).ab. /freq=2	310034
6	(algorith* or AI or artificial intelligen* or machine learning or large language or natural language or deep learning or rule based or rules based).ti,kf. or exp *decision support system/ or *information processing/ or *computer model/ or exp *computer prediction/ or *data integration/ or exp *data system/ or *data visualization/ or exp *software/ or exp *algorithm/ or exp *artificial intelligence/ or ((interpret* or decision*) adj3 (guided or support*)).mp.	686293
7	(4 and 5) or (4 and 6) or (5 and 6)	178757
8	3 and 7	28308
9	*economics/	27610

10	exp *"health care cost"/	81723
11	(economic adj2 model*).mp.	11651
12	(cost minimi* or cost-utilit* or health utilit* or economic evaluation* or economic review* or cost outcome* or cost analys?s or economic analys?s or budget* impact analys?s).ti,ab,kf.	77116
13	(life year or life years or qaly* or cost-benefit analys?s or cost-effectiveness analys?s).ab,kf.	74572
14	*health economics/ or *device economics/ or exp *economic evaluation/	103406
15	*cost/ or *budget/	23514
16	(cost* adj2 (effective* or utilit* or benefit* or minimi* or analy* or outcome or outcomes)).ab. /freq=3	54686
17	(economic* or cost or costs or costly or costing or price or prices or pricing or pharmacoeconomic* or pharmaco-economic* or expenditure or expenditures or expense or expenses or financial or finance or finances or financed or budget*).ti,kf.	402752
18	or/9-17	520261
19	8 and 18	217
20	19 not "clinicaltrials.gov".so.	206

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=3vpX1g6lWGI98IONGK8l5txVRXoyAP6wJnJg4wrqZbpSHpq0cbRKdKlf58Q6UyHtm

INAHTA

NuvoAir OR "Nuvo Air" OR lunghealth OR artiq OR "artiq.spiro" OR "artiq.pft" OR gospiro OR "Go Spiro" OR "monitored therapeutics" OR "easyone connect" OR "easy one connect" OR NuvoAirtm OR "Nuvo Airtm" OR lunghealthtm OR artiqtm OR "artiq.spirotm" OR "artiq.pfttm" OR gospirotm OR "Go Spirotm" OR "monitored therapeuticstm" OR "easyone connecttm" OR "easy one connecttm" OR "mir spiro" OR "mir spirotm" OR "medical international research spiro" OR "medical international research spirotm" OR ((mir OR "medical international research") AND ((spiro OR spirotm) AND (software OR platform))) OR easyone OR easyonetm OR "easy one" OR "easy onetm" OR spirobank OR spirobanktm OR "spiro bank" OR "spiro banktm"
link to the search
3 results

IDEAS/RePEc

((diagnosing|diagnosis|diagnostic|diagnose)+(spirometry|spirography|spirometer|spirometers|"lung function"|"pulmonary function")+(algorithm|algorithms|AI|"artificial intelligence"|"machine learning"|"large language"|"natural language"|"deep learning"|"rule based"|"rules based"))+(asthma|asthmatic|copd|"chronic obstructive"|"interstitial lung"|ipf|"idiopathic pulmonary fibrosis"|"lung disease" |"lung diseases"|"respiratory disease"|"respiratory diseases")
7 results

PEDE
algorithm|algorithms|AI|artificial intelligence|machine learning|large language|natural language|deep learning|rule based|rules based
AND
asthma|asthmatic|copd|chronic obstructive|interstitial lung|ipf|idiopathic pulmonary fibrosis|lung disease |lung diseases|respiratory disease|respiratory diseases
11 results

NHS EED
ALL FIELDS:
(diagnos* AND (spiro* OR "lung function" OR "pulmonary function")) OR ((algorith* OR AI OR "artificial intelligence" OR "machine learning" OR "large language" OR "natural language" OR "deep learning" OR "rule based" OR "rules based") AND (spiro* OR "lung function" OR "pulmonary function" OR diagnos*))
AND TITLE:
(asthma* OR copd OR "chronic obstructive" OR "interstitial lung" OR ipf OR "idiopathic pulmonary fibrosis" OR "lung disease*" OR "respiratory disease*")
33 results

CEA Registry
((diagnosing OR diagnosis OR diagnostic OR diagnose) AND (spirometry OR spirography OR spirometer OR spirometers OR "lung function" OR "pulmonary function") AND (algorithm OR algorithms or AI or "artificial intelligence" OR "machine learning" OR "large language" OR "natural language" OR "deep learning" OR "rule based" OR "rules based")) AND (asthma OR asthmatic OR copd OR "chronic obstructive" OR "interstitial lung" OR ipf OR "idiopathic pulmonary fibrosis" OR "lung disease" OR "lung diseases" OR "respiratory disease" OR "respiratory diseases")
link to the search
3 Results

Clinical effectiveness searches

The final clinical effectiveness search strategy was based around product name terms. Extensive testing was carried out to identify examples of relevant literature that did not name the relevant technology in the database records (title, abstract, keywords, and so on) but did in the full text. However, there was little evidence of this, so a product name strategy was deemed appropriate.

Database/Source	Platform/URL	Date range	Date searched	Retrieved Results
MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations	OVID	1946 to 29/8/2025	1/9/2025	29
Embase	OVID	1974 to 28/8/2025	1/9/2025	178 (119 conference abstracts, 59 articles)
Cochrane Database of Systematic Reviews	Cochrane Library (Wiley)	From inception to current	1/9/2025	1
CENTRAL	Cochrane Library (Wiley)	From inception to current	1/9/2025	29
INAHTRA	https://database.inahta.org/	Up to date	1/9/2025	3
WHO ICTRP	https://trialsearch.who.int/	Up to date	1/9/2025	(6 but ignored as all within clinicaltrials.gov results)
NIH Clinicaltrials.gov	https://clinicaltrials.gov/	Up to date	1/9/2025	16

Total number of records retrieved from all sources: 256
Total number of records after deduplication: 222

Ovid MEDLINE(R) and Epub Ahead of Print, In-Process, In-Data-Review & Other Non-Indexed Citations, Daily and Versions <1946 to August 29, 2025>

1	exp *Asthma/ or *lung diseases, obstructive/ or exp *pulmonary disease, chronic obstructive/ or exp *Lung Diseases, Interstitial/ or exp *Pulmonary Fibrosis/ or *respiratory tract diseases/ or *lung diseases/ or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ti. or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ab. /freq=3	379058
2	((asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).kf. or (exp Asthma/ or lung diseases, obstructive/ or exp pulmonary disease, chronic obstructive/ or exp Lung Diseases, Interstitial/ or exp Pulmonary Fibrosis/ or respiratory tract diseases/ or lung diseases/)) and (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis or ((lung or pulmonary or respiratory) adj3 disease*)).ab.	201639
3	1 or 2	398962
4	(NuvoAir* or Nuvo air*).mp,in.	7
5	lunghealth*.mp,in.	6
6	(computer guided or guided consultation).mp. and 3	5
7	(artiq* not (artiqo or ((artiq adj3 questionnaire) not spiro*))).mp,in.	16
8	(GoSpiro* or Monitored Therapeutics).mp,in.	3
9	((easyone* or easy one*) adj5 (software or platform or connect*)).mp,in.	0
10	(mir spiro or mir spirotm or medical international research spiro or medical international research spirotm).mp,in.	1
11	((mir or medical international research) and ((spiro or spirotm) adj5 (software or platform))).mp,in.	0
12	or/4-11	36
13	12 not ((cystic fibrosis.ti. or (cf.ti. and cystic fibrosis.mp.)) not 3)	32
14	limit 13 to yr="2000 -Current"	29

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=7CXsiObaZQ80p2WBaI05QmqxQ8Znnm6SaWjwqNctaIFEPswhaayqaMcJoDJtFQHJj

Embase <1974 to 2025 August 28>

1	exp *asthma/ or *chronic obstructive lung disease/ or *obstructive lung disease/ or exp *interstitial lung disease/ or *lung disease/ or *respiratory tract disease/ or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ti. or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ab. /freq=3	473838
2	((asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).kf. or (exp asthma/ or chronic obstructive lung disease/ or obstructive lung disease/ or exp interstitial lung disease/ or fibrosing alveolitis/ or lung disease/ or	439296

	respiratory tract disease/)) and (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis or ((lung or pulmonary or respiratory) adj3 disease*)).ab.	
3	1 or 2	609729
4	(NuvoAir* or Nuvo air*).af.	89
5	lunghealth*.af.	27
6	(computer guided or guided consultation).mp. and 3	11
7	(artiq* not (artiqo or ((artiq adj3 questionnaire) not spiro*))).af.	68
8	(GoSpiro* or Monitored Therapeutics).af.	19
9	((easyone* or easy one*) adj5 (software or platform or connect*)).af.	5
10	(mir spiro or mir spirotm or medical international research spiro or medical international research spirotm).af.	6
11	((mir or medical international research) and ((spiro or spirotm) adj5 (software or platform))).af.	0
12	or/4-11	220
13	12 not ((cystic fibrosis.ti. or (cf.ti. and cystic fibrosis.mp.)) not 3)	188
14	13 not "clinicaltrials.gov".so.	178
15	limit 14 to conference abstract	119
16	14 not 15	59

https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=4PB0vw1hwrIC5tptk90fRbBNAATeUxx841HNSJToLairUezNkdODYu1ZgqFKgNp7Y

Cochrane Library

NuvoAir* OR (Nuvo NEXT air*) OR lunghealth* OR artiq* OR "artiq.spiro" OR "artiq.pft" OR gospiro* OR "monitored therapeutics" OR ((easyone* OR (easy NEXT one*)) NEAR/5 (software OR platform OR connect*)) OR "mir spiro" OR "mir spirotm" OR "medical international research spiro" OR "medical international research spirotm" OR ((mir OR "medical international research") AND ((spiro OR spirotm) NEAR/5 (software OR platform)))

CDSR: 1, CENTRAL (after removal of NCT trials): 29

INAHTA

NuvoAir OR "Nuvo Air" OR lunghealth OR artiq OR "artiq.spiro" OR "artiq.pft" OR gospiro OR "Go Spiro" OR "monitored therapeutics" OR "easyone connect" OR "easy one connect" OR NuvoAirtm OR "Nuvo Airtm" OR lunghealthtm OR artiqtm OR "artiq.spirotm" OR "artiq.pfttm" OR gospirotm OR "Go Spirotm" OR "monitored therapeuticstm" OR "easyone connecttm" OR "easy one connecttm" OR "mir spiro" OR "mir spirotm" OR "medical international research spiro" OR "medical international research spirotm" OR ((mir OR "medical international research") AND ((spiro OR spirotm) AND (software OR platform))) OR easyone OR easyonetm OR "easy one" OR "easy onetm" OR spirobank OR spirobanktm OR "spiro bank" OR "spiro banktm"

link to the search

3 results

Clinicaltrials.gov & ICTRP

NuvoAir OR "Nuvo Air" OR lunghealth OR artiq OR "artiq.spiro" OR "artiq.pft" OR gospiro OR "Go Spiro" OR "monitored therapeutics" OR "easyone connect" OR "easy one connect" OR NuvoAirtm OR "Nuvo Airtm" OR lunghealthtm OR artiqtm OR "artiq.spirotm" OR "artiq.pfttm" OR gospirotm OR "Go Spirotm" OR "monitored therapeuticstm" OR "easyone connecttm" OR "easy one connecttm" OR "mir spiro" OR "mir spirotm" OR "medical international research spiro" OR "medical international research spirotm" OR ((mir OR "medical international research") AND ((spiro OR spirotm) AND (software OR platform)))

Clinicaltrials.gov: 16 results (ICTRP: 6 resilts, all within the clinicaltrials.gov results, so ignored)

link to the Clinicaltrials.gov search

Clinical effectiveness – additional Spirobank/EasyOne test searches

For the additional targeted searches, a single reviewer (RP) screened 77 records for relevance to the scope, with 5 full records retrieved and reviewed by 2 reviewers (PL, RP). Only one relevant reference was identified (Castro et al. 2024), which captured evidence relating to patient experience only.

Embase <1974 to 2025 August 28>

1	exp *asthma/ or *chronic obstructive lung disease/ or *obstructive lung disease/ or exp *interstitial lung disease/ or *lung disease/ or *respiratory tract disease/ or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ti. or (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).ab. /freq=3	473838
2	((asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis).kf. or (exp asthma/ or chronic obstructive lung disease/ or obstructive lung disease/ or exp interstitial lung disease/ or fibrosing alveolitis/ or lung disease/ or respiratory tract disease/)) and (asthma* or copd or chronic obstructive or interstitial lung or ipf or idiopathic pulmonary fibrosis or ((lung or pulmonary or respiratory) adj3 disease*)).ab.	439296
3	1 or 2	609729
4	di.fs. or (diagnos* or detect*).ti. or (diagnos*.kf. and diagnos*.ab.) or diagnos*.ab. /freq=3	5296997

5	spiro*.mp. or (pulmonary function or lung function).ti,hw,kf. or (pulmonary function or lung function).ab. /freq=2	310034
6	(easyon or easyonpc* easy on* pc or easy onpc*).af.	7
7	ndd med*.af.	167
8	ndd.dm,dv. or (ndd.af. and spiro*.mp.)	260
9	easyone*.af. or easy one*.dm,dv. or (easy one*.af. and spiro*.mp.)	502
10	((mir adj4 spiro*) or spirobank*).af.	299
11	or/6-10	901
12	(algorith* or AI or artificial intelligen* or machine learning or large language or natural language or deep learning or rule based or rules based).ti,kf. or exp decision support system/ or information processing/ or data analysis/ or computer model/ or exp computer prediction/ or data integration/ or exp data system/ or data visualization/ or exp software/ or exp algorithm/ or exp artificial intelligence/ or *primary care/ or ((interpret* or decision*) adj3 (guided or support*)).mp.	2401199
13	(3 and 12 and (4 or 5) and 11) not "clinicaltrials.gov".so.	90
14	limit 13 to yr="2018 -Current"	62

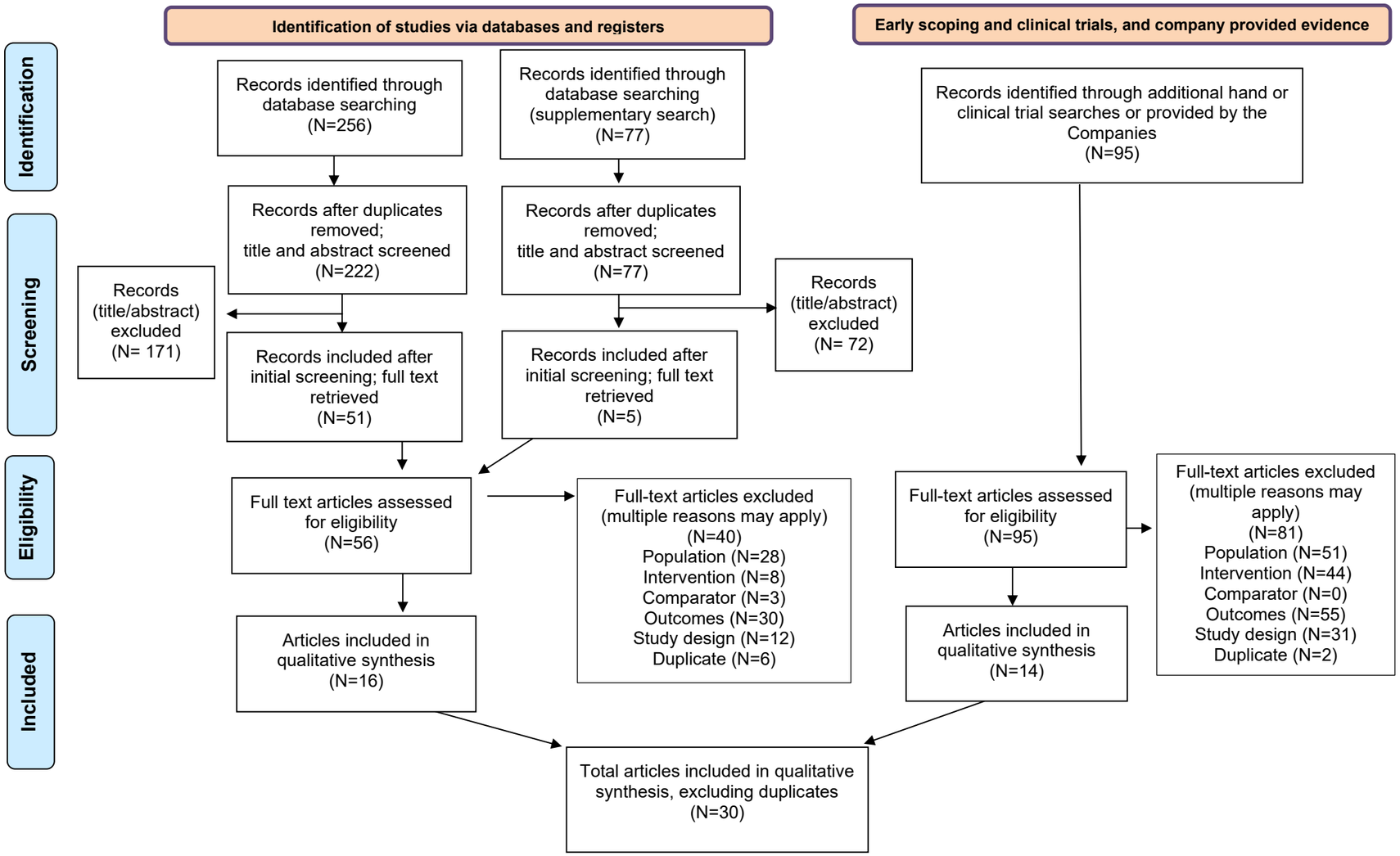
https://ovidsp.ovid.com/ovidweb.cgi?T=JS&NEWS=N&PAGE=main&SHAREDSEARCHID=5kwsuIK7tzbqIxEq6FIJLvvLAPL4msbw7f04MsHgdOYeqr9UVnG1FNtzeIhXhuzvI

Clinicaltrials.gov

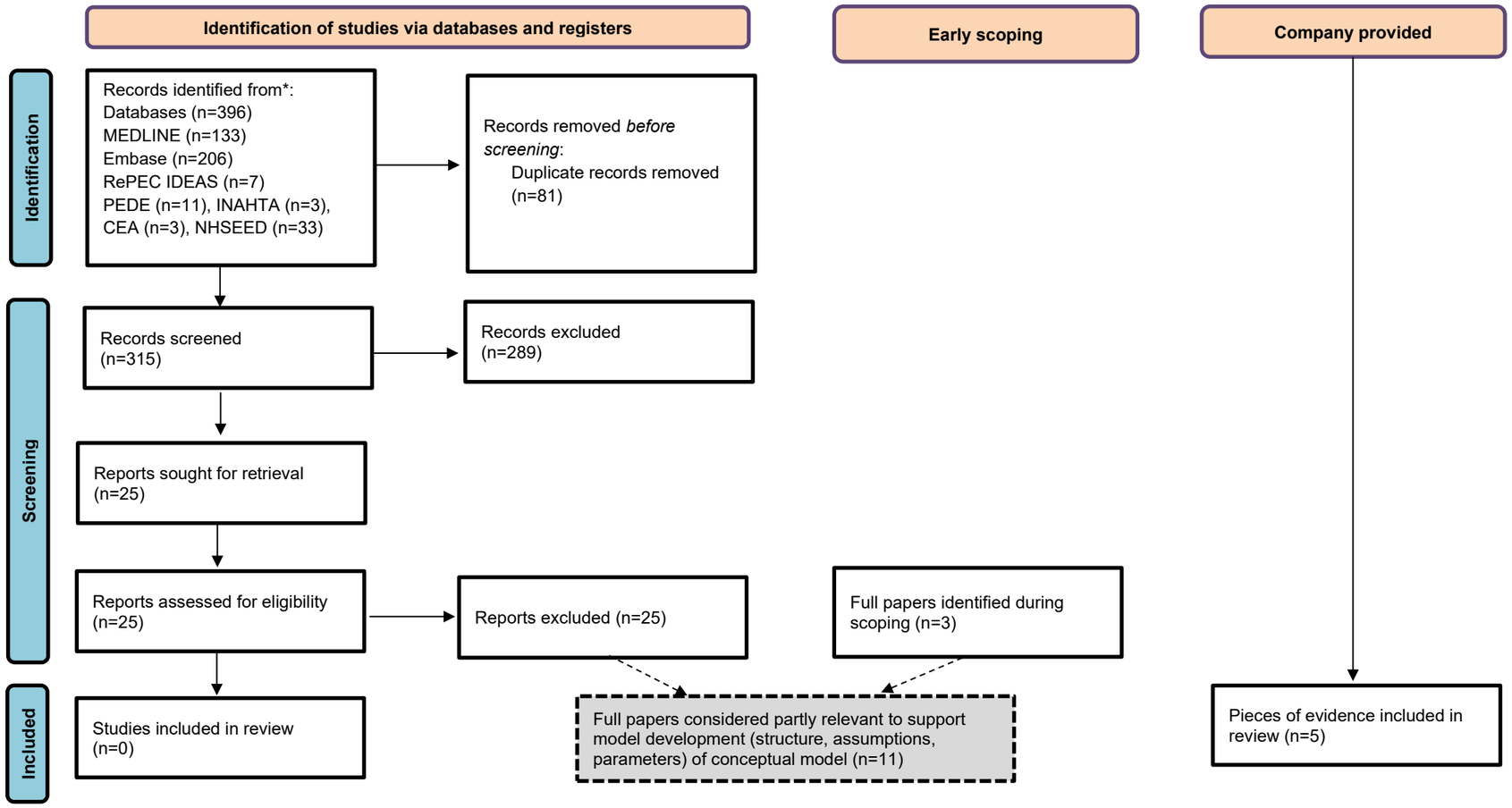
(asthma OR copd OR "chronic obstructive" OR "interstitial lung" OR ipf OR "idiopathic pulmonary fibrosis" OR "lung disease" OR "respiratory disease") | (easyone OR easyonetm OR "easy one" OR "easy onetm" OR spirobank OR spirobanktm OR "spiro bank" OR "spiro banktm")

https://clinicaltrials.gov/search?intr=(easyone%20OR%20easyonetm%20OR%20%22easy%20one%22%20OR%20%22easy%20onetm%22%20OR%20spirobank%20OR%20spirobanktm%20OR%20%22spiro%20bank%22%20OR%20%22spiro%20banktm%22)&cond=(asthma%20OR%20copd%20OR%20%22chronic%20obstructive%22%20OR%20%22interstitial%20lung%22%20OR%20ipf%20OR%20%22idiopathic%20pulmonary%20fibrosis%22%20OR%20%22lung%20disease%22%20OR%20%22respiratory%20disease%22)

Appendix A2: PRISMA diagram: clinical evidence



Appendix A3: PRISMA diagram: economic evidence



Appendix A4: Study characteristics of included studies (N=30)

#	Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
1.	ArtiQ.Spiro (Clario) *Funding:* not reported. *Declaration of interests:* two authors affiliated with ArtiQ.	Adams (Practice Nurse, 2024; 22-25)[Editorial] Prospective cross-sectional cohort UK	n=51 (adults, suspected of having various lung conditions, but also included those with known asthma) Setting: N=2 primary care services (Sunderland, UK) Recruitment period: NR	Intervention: SpiroConnect (ArtiQ.Spiro) Comparator: Interpretation spirometry without AI support	Quality analysis and interpretation of the spirometry session and the time taken to interpret the results with and without AI support (whether the AI physiological interpretation matched clinician interpretation). Confidence of the clinicians in their interpretation and in the AI process was evaluated. Also includes if management plan was changed based on AI report. Follow up: NR	Two participating clinicians tested and analysed participants spirometry results, one experienced ARTP accredited nurse and the other a primary care physician in the process of obtaining ARTP accreditation which may not represent spirometry performed or interpreted by less trained individuals. The results were not independently assessed by an expert, so no “ground truth” was established, preventing the accuracy comparison of the technology and clinicians' assessments.
2.	ArtiQ.Spiro (Clario) *Funding:* not reported. *Declaration of interests:* several authors affiliated with ArtiQ, AstraZeneca, Kessel-lo (reported in “Info and Metrics” online).	De Vos (Eur Resp J, 2023) [Abstract] Qualitative cross-section cohort Belgium	n=NR (GPs diagnosing COPD) Setting: N=18 GP practices Recruitment period: NR	Intervention: ArtiQ.Spiro Comparator: None	Understand the current delivery of and barriers to performing spirometry Assess added value of AI-based software quality assessment and interpretation of curves to support diagnosis. Follow-up:none.	Limited detail in abstract. Proportion flagged as having COPD by ArtiQ reported but not independently assessed “ground truth”.
3.	ArtiQ.Spiro (Clario) *Funding:* National Institute for Health and Care Research and NIHR Leicester Biomedical Research Centre - Respiratory theme. *Declaration of interests:* several authors affiliated with ArtiQ, ArtiQ NV, AstraZeneca, Clario (as reported in Supplementary Material 2).	Doe (NEJM AI, 2025a; 8) RCT (superiority; 10% difference in correct diagnosis prediction performance) [NCT05933694] UK	n=234 primary care clinicians. Setting: N=NR, primary care settings, study sponsored by Royal Brompton & Harefield NHS Foundation Trust. Recruitment period: June 2023 to March 2024	Intervention: Spirometry interpretation with AI assistance (ArtiQ.Spiro) Comparator: Spirometry interpretation without AI assistance (ArtiQ.Spiro)	Primary: Preferred diagnosis prediction performance, measured as the percentage of cases in which the preferred diagnosis agreed with the reference diagnosis predetermined by expert pulmonologists (see comments). Secondary: Performance in differential diagnosis prediction, technical quality assessment, pattern interpretation, and self-rated confidence in interpretation. Follow-up: none.	Recruitment target increased to account for higher than expected non-completion rate. Clinicians in study were required to have to access spirometry traces on the study platform. Clinician’s task to assess 50 real-world patient spirometry records selected from community-based respiratory clinics in Hillingdon borough. Reference standard for diagnosis made by a panel of three respiratory specialists from the clinical care team with access to medical notes and results of relevant investigations but without access to AI report.
4.	ArtiQ.Spiro (Clario) *Funding:* National Institute for Health Research AI Award in Health and Care. *Declaration of interests:* several authors affiliated with ArtiQ, KU Leuven, Clario.	Doe (Am J Resp Crit Care Med, 2025b; 211) [Abstract] Qualitative focus group. Location NR but given funding presumed to be UK.	n=9 adults who had undergone spirometry Setting: Online focus group in primary care. Recruitment period: NR	Intervention: ArtiQ.Sprio Comparator: None.	To understand patient perspectives on AI decision support software in aiding clinicians to perform and interpret spirometry. Follow-up: none	Limited detail in abstract. Unclear if ArtiQ.Spiro was under scrutiny by the focus group or AI in general.

#	Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
5.	ArtiQ.Spiro (Clario) *Funding:* not reported. *Declaration of interests:* authors affiliated with ArtiQ, Clario.	Hayes (PCRS, 2025b) [Poster] Service evaluation and clinician survey. UK	Participants: n=NR, NHS Band 3 respiratory care and support workers and Band 6 or 7 ARTP certified respiratory nurse specialists. Setting: N=NR, County Durham and Darlington Foundation Trust community respiratory services Recruitment period: NR	Intervention: ArtiQ.Spiro NHS Band 3s performing with Band 6 or 7 supervision and interpretation. Comparator: NHS Band 6 or 7s performing and interpreting spirometry without AI.	Not specified but findings describe efficiencies in service delivery with adoption of AI (effect on appointment times, testing capacity, staff requirements (skills/banding) Follow-up: none.	Limited detail in poster. Poster details releasing of clinical hours, however no detail is provided relating to how this resource was otherwise used, such as whether this was used to increase the testing capacity further or redistributed to other healthcare services.
6.	ArtiQ.Spiro (Clario) *Funding:* Provincie Vlaams-Brabant. *Declaration of interests:* authors affiliated with ArtiQ, ArtiQ NV.	Maes (Am J Resp Crit Care Med, 2024; A1461) [Abstract] Diagnostic concordance Belgium	Participants: n=NR, GPs Setting: N=6 primary care practices Recruitment period: NR	Intervention: ArtiQ.Spiro Comparator: expert panel of 3 pulmonologists without AI.	Accuracy of GP assessment of spirometry curves with and without AI Follow-up: none	Limited detail in abstract. Diagnostic status (undiagnosed and diagnosis) or type of respiratory disease suspected not specified for patients tested. Number of patients tested not specified. GP experience with spirometry not discussed. Gold standard comparison to expert panel of 3 pulmonologists.
7.	ArtiQ.Spiro (Clario) *Funding:* not reported *Declaration of interests:* not reported	Polaris (ERS Conference 2025) [Abstract] Retrospective comparative cohort UK	Participants: n=248 patients attending direct access COPD pathway. Setting: NR, COPD diagnostic pathway Recruitment period: between 2022 and 2024, no further details provided	Intervention: ArtiQ.Spiro Comparator: interpretations by ARTP-registered clinicians and final diagnostic pathway outcomes to determine concordance	Agreement between a 'normal' AI interpretation and 'normal' clinician-reported spirometry and pathway outcome. Clinical user experience feedback on Artiq.Spiro. Follow-up: none	Limited detail in abstract. Abstract submitted for conference held 27 September to 1 October 2025, details provided by Company.
8.	ArtiQ.PFT (Clario) *Funding:* ArtiQ *Declaration of interests:* several authors affiliated with ArtiQ.	Ray (Am J Resp Crit Care Med, 2022; A4884) [Abstract] Retrospective comparative cohort Location: NR, UK biobank used	Participants: n=109 (deceased subjects selected from UK Biobank dataset with ILD as cause of death and spirometry in past 7 years with no ILD diagnosis at last spirometry). Setting: NR Recruitment period: NR	Intervention: ArtiQ.PFT spirometry algorithm component Comparator: Standard care (Biobank records)	Not specified but relating to diagnostic concordance. Mortality, duration between AI disease detection vs official diagnosis made (based on Biobank inputs). Follow-up: none	Limited detail in abstract. Retrospective deceased BioBank UK volunteers. Therefore, no prospective follow-up to determine impact of change in diagnosis or management.

#	Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
9.	ArtiQ.Spiro (Clario) *Funding:* authors report no funding. *Declaration of interests:* two authors affiliated with ArtiQ	Smets (Am J Resp Crit Care Med, 2025; A3652) [Abstract] Service evaluation UK	Participants: n=19 patients undergoing spirometry, 12 patients had bronchodilator response testing 1 healthcare assistant, unregistered on the National Spirometry Register, provided with local training and competency assessment. Setting: NR, primary care Recruitment period: NR	Intervention: ArtiQ.Spiro Comparator: none	Not specified but spirometry quality parameters reported. Follow-up: none	Limited detail in abstract. Grading of spirometry by unregistered clinician using ArtiQ.Spiro.
10.	ArtiQ.Spiro (Clario) *Funding:* NHS Transformation Directorate and the NIHR through an AI Award in Health and Care *Declaration of interests:* several authors affiliated with ArtiQ	Sunjaya (ERJ Open Res, 2025) Observational retrospective diagnostic study with blinded analysis [NCT05648227] UK	Participants: n=1,113 adult primary care spirometry datasets Setting: N=NR, Recruited from London, Hillingdon. Recruitment period: September 2015 to March 2019	Intervention: ArtiQ.Spiro (supervised random forest machine learning) for diagnosis and assessment of spirometry quality. Comparator: Consensus of AI with reference standards provided by expert pulmonologists with access to primary and secondary care medical notes and results of relevant investigations.	Cross tabulation of the index test results by the results of the reference standard for COPD and other respiratory disease categories. Follow-up: none.	Reporting was done in accordance with STARD guidelines. Discrepancies between the datasets used to train the AI and current study population data were reported 1) the technical quality of spirometry of current study thought to be poorer as was performed by non-physiologists without comprehensive training or supervision by dedicated respiratory physiologists; 2) original training set comprised entirely of patients of white origin, whereas 23.2% of the patients included in the dataset for this study were of other ethnicity; 3) the datasets for this study originated from primary care thought to represent more common respiratory conditions than the rarer conditions seen in secondary and tertiary care (used to train AI). Authors noted that spirometry data was captured using an EasyOne spirometer and data held on the EasyOne Connect software database. As authors note that the raw spirometry data was using by the ArtiQ.Spiro software, the EAG assume that any algorithm in the NDD technology was not used in this diagnostic validation study.
11.	ArtiQ.Spiro (Clario) *Funding:* NR *Declaration of interests:* several authors affiliated with ArtiQ	Willaert (Int Prim Care Resp Group, 2023) [Abstract] Qualitative: semi-structured interviews Belgium	Participants: n=8 GPs who perform spirometry Setting: N=3 GP practices Recruitment period: NR	Intervention: not stated but authors affiliated with ArtiQ Comparator: none	GP views on general role of spirometry in primary care, limiting and facilitating factors, and how GPs might be supported in doing and interpreting spirometry	Limited detail in abstract. Part of a larger study on use of spirometry supported by AI guided software.

#	Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
12.	GoSpiro (Monitored Therapeutics) *Funding:* Midmark Corporation *Declaration of interests:* authors affiliated with Midmark Corporation and Monitored Therapeutics.	Rydberg (COPD, 2023; 437-443) [NCT04369885] Pilot prospective non-comparative cohort study. US	Participants: n=12 (14 enrolled, 2 withdrew for reasons unrelated to the study) adults aged 40-80 years with spirometry confirmed COPD. Setting: N=1 clinical site, home testing Recruitment: from 23 July 2020 to 19 February 2021.	Intervention: in-home telemonitoring system with 3 components: a home spirometer (GoSpiro), a Bluetooth-enabled home pulse oximeter (NoninConnect), and a tablet-based data collection system with avatar-assisted technology (GoHome). Comparator: NR	Impact on COPD Assessment Test, measurement collection adherence, patient satisfaction survey, communication frequency preference, self-reported exacerbations. Follow-up: 12-week programme.	Evidence in a diagnosed population, mixed intervention used for home monitoring. 10 participants completed the 12-week study. Outcomes in scope relate only to user perspective and usability.
13.	LungHealth (LungHealth Ltd.) *Funding:* NR *Declaration of interests:* author affiliated with LungHealth	Angus (Am J Resp Crit Care Med, 2019; A3338) [Abstract] Service evaluation UK	Participants: n=741 adult patients on COPD registry Setting: N=54 practices presumed primary care from introduction Recruitment period: NR	Intervention: Clinical review with LungHealth computer-guided consultation. Comparator: none	Not specified but diagnostic concordance, inhaler technique, and optimisation of interventions are discussed. Follow-up: none	Limited detail in abstract. Lacking long-term follow up to determine impact of change in diagnosis or management.
14.	LungHealth (LungHealth Ltd.) *Funding:* NR *Declaration of interests:* NR	Angus (Am J Respir Crit Care Med, 2017; A1736) [Abstract] Service evaluation UK	Participants: n=2,704 adults with COPD Setting: N=109 practices, setting not explicitly specified Recruitment period: NR	Intervention: Clinical review with LungHealth computer-guided consultation. Comparator: none	Not specified but diagnostic concordance, inhaler technique, and optimisation of interventions discussed. Follow-up: none	Limited detail in abstract. Lacking long-term follow up to determine impact of change in diagnosis or management.
15.	LungHealth (LungHealth Ltd.) *Funding:* AstraZeneca, Boehringer Ingelheim and GlaxoSmithKline provided unrestricted grants. *Declaration of interests:* authors report: "*The software was developed personally with no NHS investment and four of the authors (RMA, LD, EM and MGP) have formed a company LungHealth to commercialise the software as the NHS would not support the development cost. We performed the research in our professional capacity and LungHealth is not mentioned in the paper*"	Angus (Prim Care Respir, 2012; 425-430) Service evaluation UK	Participants: n=293 adults diagnosed with COPD undergoing routine clinical review with 18 nurses, of which 11 nurses had specialty respiratory training Setting: N=16 primary care practices Recruitment period: NR	Intervention: Routine clinical review with LungHealth computer-guided consultation. Comparator: none.	Number of spirometry tests performed, change in management or diagnosis, clinician feedback (Likert scale), staff training time, appointment duration. Follow-up: none	Evidence in a population with a diagnosis of COPD. Full assessment reported on 236 patients, unclear if remaining 57 had spirometry but not a full assessment. Lacking long-term follow up to determine impact of change in diagnosis or management.

#	Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
16.	LungHealth (LungHealth Ltd.) *Funding:* NR *Declaration of interests:* authors affiliated with LungHealth.	Chakrabarti (Prim Care Resp Med, 2025a; 12) Service evaluation UK	Participants: n=5,221 adults with previous diagnosis of COPD (identified using a bespoke MIQUEST software tool) invited for clinical review with computer-guided consultation. Setting: N=254 GP surgeries (UK) Recruitment period: March 2021 and March 2023	Intervention: Adjunct clinical review with LungHealth computer-guided consultation. Comparator: None	The role of the computer-guided consultation in improving: diagnostic accuracy; detection of comorbidity; pharmacological/ non-pharmacological management of COPD. Follow-up: none	Evidence in a population with existing diagnosis of COPD. Lacking long-term follow up to determine impact of change in diagnosis or management. Preliminary data exists detailing the health economic benefits of computer-guided consultation during initial feasibility studies only (not for current study).
17.	LungHealth (LungHealth Ltd.) *Funding:* NR *Declaration of interests:* several authors affiliated with LungHealth	Chakrabarti (PCRS, 2024; 296) [Poster] Service evaluation UK	Participants: n=847 adult patients on COPD register Setting: N=17 practices in NHS Bedfordshire Recruitment period: March 2019 to March 2020	Intervention: Adjunct clinical review with LungHealth computer-guided consultation. Comparator: none	Not specified but findings relating to improvement of diagnostic accuracy and management; and health economic benefits including improvement of diagnosis (for example, identifies COPD as over diagnosed and the burden of care). Follow-up: none	Limited detail in poster. No comparison to reference standard. Lacking long-term follow up to determine impact of change in diagnosis or management
18.	LungHealth (LungHealth Ltd.) *Funding:* "*the majority of the data gathered for this publication was funded by GlaxoSmithKline Uk Ltd, and collaboratively developed and delivered with NSHI Ltd as a service to medicine*" *Declaration of interests:* NR	O'Driscoll (Nat Serv for Health Improv, 2024) [Poster] Service evaluation UK	Participants: n=1,877 adult patients with COPD (GOLD group D) on the COPD register were invited for review Setting: N=26 primary care practices (Norfolk and Waveney) Recruitment period: NR	Intervention: Adjunct clinical review with LungHealth computer-guided consultation. Comparator: none.	Not specified. But relating to diagnostic accuracy with COPD. Follow-up: none.	Limited detail in poster. 1,877 were invited for review of whom 1,661 underwent review remotely. Lacking long-term follow up to determine impact of change in diagnosis or management.
19.	LungHealth (LungHealth Ltd.) *Funding:* NR *Declaration of interests:* NR, authors affiliated with LungHealth	Thompson (Thorax, 2013a; S71) [Abstract] Service evaluation UK	n=2,000 patients on COPD registers Setting: 78 practices (presumed primary care) region(s) not specified (authors based in Liverpool and Dartford). Recruitment period: NR	Intervention: Computer-guided consultation (named technology not specified, assumed to be LungHealth due to reporting and author affiliations) Comparator: none	Not specified but findings include treatment/management modifications to existing care. Follow-up: not reported	Limited detail in abstract. Lacking long-term follow up to determine impact of change in diagnosis or management
20.	LungHealth (LungHealth Ltd.) *Funding:* Boehringer Ingelheim and AstraZeneca UK *Declaration of interests:* NR, authors affiliated with LungHealth	Thompson (Am J Resp Crit Care Med, 2013b; A2829) [Abstract] Service evaluation. UK	Participants: n=417 adult patients attending for COPD review Setting: N=13 practices (presumed primary care) Recruitment period: NR	Intervention: Computer-guided consultation (named technology not specified, assumed to be LungHealth due to reporting and author affiliations) Comparator: none	Not specified but findings include diagnostic revision, and treatment or management modifications to existing care. Follow-up: none	Limited detail in abstract. Lacking long-term follow up to determine impact of change in diagnosis or management

#	Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
21.	Mixed intervention: ArtiQ.Spiro (Clario) and LungHealth (LungHealth Ltd.) *Funding:* NR *Declaration of interests:* authors affiliated with LungHealth Ltd, Chiesi Ltd, Fuller and Forbes Healthcare Group	Chakrabarti (PCRS, 2025d) Service evaluation UK	Participants: n=103 adults with suspected COPD awaiting spirometry Setting: N=17 primary care practices within the Fuller and Forbes Healthcare Group (UK wide) Recruitment: November 2024 to December 2024	Intervention: LungHealth computer-guided consultation and spirometry using ArtiQ.Spiro spirometry software (mixed intervention) with BDR testing Comparator: none	Outcomes: Proportion of patients diagnosed with COPD, spirometry results, breathlessness, sex and GOLD staging of patients diagnosed with COPD. Follow-up: none	Mixed intervention, unable to attribute results to single technology. Only evidence identified for LungHealth in a pre-diagnosed population in Scope of this EVA.
22.	Spirobank Smart (MIR) *Funding:* AstraZeneca funded the study, was involved in the study design and study conduct. AstraZeneca was given the opportunity to review the manuscript before submission and funded medical writing support. *Declaration of interests:* multiple authors with AstraZeneca.	Castro (Ther Adv Resp Dis, 2024; 1-17) Multicentre, prospective non-comparative, proof of concept study (iPREDICT). US	Participants: n=132 enrolled (108 completed training and were onboarded) aged ≥ 12 years with severe uncontrolled asthma. Setting: N=7 sites, home testing Recruitment period: from December 2017 to December 2018.	Intervention: spirometer, vital sign monitor, sleep monitor, connected inhaler devices, and two mobile applications with embedded patient-reported outcome questionnaires. Comparator: NR.	Primary endpoint: asthma event: symptom worsening logged by patients ; PEF <65%, or FEV1 <80%, increased SABA use. User experience surveys at weeks 4 and 20, and an exit interview. Patient compliance with study. Follow-up: 24-week programme.	Algorithm development and proof of concept study "*for the individualized PREdiction of DIsease Control using digital sensor Technology (iPREDICT) program aimed to employ sensors and devices to generate novel, integrated data and facilitate a precise, digitized analysis of disease characteristics, asthma triggers, and health status to establish a prognostic model of disease control by measuring departures from individual, base-line data while imposing minimal device burden*". Authors noted: *"Compensation to patients for their participation may also have played a role, as withdrawal rates declined by 19% after the initial compensation at Weeks 6–7 and decreased further after the second compensation at Week 12. Therefore, compensation mechanisms may need to be integrated with the application of digital tools to enhance utilization compliance and improve clinical outcomes."*
23.	Spirobank Smart (MIR) *Funding:* NIHR Research for Patient Benefit Grant (NIHR203591) and supported by the Manchester NIHR Biomedical Research Centre (grant no. BRC-1215-20007, and NIHR203308), Asthma UK/Innovate (grant no. AUK-PG-2018-406) and North West Lung Centre Charity *Declaration of interests:* authors declared "*no competing interests*"	Khatoon (medRxiv, 2025) [Pre-print] Qualitative semi-structured interview study UK	Participants: n=15 adult patients with asthma (GP suspected). Setting: Interviews undertaken at the Manchester University NHS Foundation Trust Recruitment period: August 2023 to May 2024	Intervention: Home-based diagnosis using Spirometry (MIR Spirobank Smart) and FeNO (NOBreath, Bedfont, UK) devices and supporting mobile supporting apps. Comparator: none	Not explicitly stated, study objective includes exploring patients' views on performing spirometry at home during the asthma diagnostic process. Three themes emerged: • Perceived values of, and burdens of home asthma testing • Views of device usability and acceptability • Information and support needs Follow-up: none	Preprint posted by the author on www.medRxiv.org without peer review. Invitations sent to 51 participants in a larger study. Unclear why 10 of 26 respondents did not participate (1 of 16 files corrupted to leave 15). Study limited to patients *suspected of having asthma by a GP.*

#	Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
24.	Spirobank Smart (MIR) *Funding:* "*unrestricted grant by SIMESA SpA (AstraZeneca Group)*" *Declaration of interests:* two authors affiliated with SIMESA SpA (AstraZeneca Group)	Lusuardi (Chest, 2006; 844-852) Prospective RCT, and parallel observational (feasibility) study Italy	Participants: RCT: n=333 adults from 104 physicians with symptoms suggestive of COPD or Asthma;Observational: n=2,055, participants recruited by 236 GPs who continued after the run-in period (May to October 2002) included those with previous asthma/COPD diagnosis. Setting: N=570 GPs (presumed individual practice) Recruitment: November 2002 to July 2003 for RCT and observational study.	Intervention: Conventional evaluation with additional MIR Spirobank spirometry Comparator: Conventional evaluation (without spirometry)	Degree of diagnostic concordance of intervention versus compactor group diagnoses compared against hospital based pulmonary specialist diagnosis with access to full respiratory function test equipment (Gold standard) Follow-up: none	Study population randomised into two groups (1:1) using an interactive voice responding systems. Authors reported that the randomisation procedure proved to be complicated and poorly applied. RCT not allocated 1:1 into groups initially (conventional n=83, conventional + spirometry n=250), of whom 109 did not have complete evaluation, resulting in 224 patients of whom 89 were randomisation violators. QA of spirometry reported to be poorly managed Study reported to be under powered (potential type II error) to show a difference between two groups.
25.	NuvoAir (NuvoAir) *Funding:* authors report no funding. *Declaration of interests:* two authors affiliated with NuvoAir	Coughlin (Am J Resp Crit Care Med, 2021; A3188) [Abstract] Qualitative survey UK	Participants: n=8 paediatric patients with asthma and n=10 parents/caregivers. Setting: Home testing Recruitment period: NR	Intervention: NuvoAir Home platform (smartphone application, Bluetooth spirometer and physician portal). Comparator: None.	Acceptability, including: • Ease of setup • Ease of use Follow-up: none	Limited detail in abstract. 71 Surveys sent, 18 were returned and included if at least one question was answered. Missing answers were assigned a rating of strongly disagree.
26.	NuvoAir (NuvoAir) [redacted]*Funding:* [redacted] *Declaration of interests:* [redacted]	Gray (RCPCH, 2026) [Abstract, AIC] [redacted]	Participants: [redacted] Setting: [redacted] Recruitment period: [redacted]	Intervention: [redacted] Comparator: [redacted]	[redacted] Follow-up: [redacted]	Limited detail in abstract including missing figures and tables.

#	Technology (manufacturer)	Study name, design and location	Participants and setting	Intervention(s) and comparator	Outcomes measures and follow up	EAG comments
27.	NuvoAir (NuvoAir) *Funding:* Boehringer Ingelheim and NuvoAir. Boehringer Ingelheim and NuvoAir had no role in the design, analysis or interpretation of the results. Boehringer Ingelheim was given the opportunity to review the manuscript for medical and scientific accuracy relating to BI substances and intellectual property considerations. *Declaration of interests:* four authors were employed by the General Practitioners Research Institute (GPRI) who performed the study. JK holds 72.5% shares of GPRI. Multiple authors with AstraZenica, Boehringer Ingelheim, Chiesi Pharmaceuticals and other pharmaceutical companies.	Kocks (Research Square, 2023; 1-27) [NCT05162157] Cross-sectional cohort mixed-methods Location: The Netherlands and Sweden	Participants: n=140 adults (aged 16 years and older) with an asthma or COPD related indication, including patients who were familiar with spirometry and those who were not. Focus group: n=3 healthcare professionals from different participating Dutch practices Setting: home testing. Recruitment period: NR	Intervention: NuvoAir Air Next spirometer plus NuvoAir home smartphone app. May have been asked to perform pre and post bronchodilator spirometry depending on usual care. Comparator: FEV1 and FVC values from general practice setting, grading and interpretation by expert panel (n=3, reference standard)	Healthcare professionals and participants rating of home spirometry as feasible and if added value for asthma and COPD monitoring or diagnosis in primary care. Follow-up: NR	Supplied paper is a pre-print not peer reviewed by a journal. From clinical tirlas.gov: study completed in December 2022 with no results posted.
28.	NuvoAir (NuvoAir) *Funding:* none reported *Declaration of interests:* all authors affiliated with NuvoAir	Parrott (Eur Resp J, 2023; PA1583) [Abstract] Retrospective non-comparative cohort UK	Participants: n=40 adults with uncertain diagnosis of asthma (50%) or with uncontrolled symptoms (50%). Setting: Home testing asthma programme Recruitment period: participants who completed the program by 31 January 2023, starting period not defined	Intervention: NuvoAir 12-week asthma program supported virtually by physiologists. Comparator: None	Not specified but relating to diagnostic accuracy, spirometry quality, optimising treatment patient experience. Follow-up: 12-week asthma programme	Limited detail in abstract. Lacking long-term follow up to determine impact of change in diagnosis or management.
29.	NuvoAir (NuvoAir) *Funding:* NR *Declaration of interests:* all authors affiliated with NuvoAir	Robshaw (Eur Resp J, 2024; OA4592) [Abstract] Service evaluation UK	Participants: n=120 patients (asthma) Setting: Home testing Recruitment period: NR	Intervention: NuvoAir physiologist-led home spirometry assessment 12-week program Comparator: None	Outcomes reported include diagnosis confirmation, medication optimisation, onward referral. Follow-up: 12-week asthma programme	Limited detail in abstract. Lacking long-term follow up to determine impact of change in diagnosis or management.
30.	NuvoAir (NuvoAir) *Funding:* [redacted] *Declaration of interests:* [redacted]	Tuli (BTS, 2025) [Abstract, AIC] [redacted]	Participants: [redacted] Setting: [redacted] Recruitment period: [redacted]	Intervention: [redacted] Comparator: [redacted]	Outcomes reported: [redacted] Follow-up: [redacted]	Limited detail in abstract, unpublished provided by Company. [redacted]

Abbreviations: AI, artificial intelligence; ARTP, Association for Respiratory Technology and Physiology; BDR, bronchodilator reversibility; COPD, chronic obstructive pulmonary disease; FeNO, fractional exhaled nitric oxide; FEV1, forced expiratory volume in one second; FVC, forced vital capacity; NR, not reported; PEF, peak expiratory flow; RCT, randomised controlled trial; SABA, short-acting beta-2 agonist

Appendix A5: Excluded studies (N=149)

#	Technology	Source	Study	Publication type	Reasons for exclusion
1.	ArtiQ (Clario)	EAG scoping searches	Beverin (Frontiers in Medicine, 2023; p1174631)	Full publication	Outcomes: no outcomes in Scope reported Study design: machine-learning development
2.	ArtiQ (Clario, assumed from author affiliations)	EAG clinical evidence search	Cuyvers (Am J Resp Crit Care Med, 2025; A7946)	Abstract	Population: not explicit (patients enrolled in clinical trials) Outcomes: reporting quality of spirometry test only Study design: AI development
3.	ArtiQ (Clario, assumed from author affiliations)	EAG scoping searches	Graham (Eur Resp J, 2022; 2435)	Abstract	Outcomes: no outcomes in Scope Study design: AI tool used to develop reviewer consensus on spirometry test quality metrics
4.	ArtiQ (Clario)	EAG scoping searches	Doe (Br J GP, 2023a;1-9)	Full publication	Outcomes: no outcomes in Scope reported
5.	ArtiQ (Clario)	EAG clinical evidence search	Doe (Eur Resp J, 2023b; PA534)	Abstract	Outcomes: no outcomes in Scope reported, Duplicate: results reported in full publication Doe (2023a)
6.	ArtiQ (Clario)	EAG scoping searches	Elmahy (ERS Int Congress 2023)	Poster	Study design: AI development and validation study
7.	ArtiQ (Clario)	EAG scoping searches	Gompelmann (Thorax, 2025; 80(7):445-450)	Full publication	Intervention: ArtiQ PFT Outcomes: not reported exclusively for spirometry
8.	ArtiQ (Clario)	EAG scoping searches	Krauss (PLoS ONE, 2025; e0316484)	Full publication	Outcomes: no outcomes in Scope reported Study design: study protocol
9.	ArtiQ (Clario, assumed from author affiliations)	EAG clinical evidence search	Sunjaya (Eur Resp J, 2024; OA1047)	Abstract	Study design: full results reported in Sunjaya 2025
10.	ArtiQ PFT (Clario, assumed from author affiliations)	EAG scoping searches	Das (ERJ, 2019; PA2227)	Abstract	Intervention: ArtiQ PFT (assumed from use of full PFT data) Outcomes: no outcomes in scope reported Study design: AI validation
11.	ArtiQ PFT (Clario, assumed from author affiliations)	EAG scoping searches	Das (Eur Resp J, 2020; 2000603)	Full publication	Intervention: ArtiQ PFT (assumed from use of full PFT data) Study design: Lab-based AI development and validation
12.	ArtiQ PFT (Clario, assumed from author affiliations)	EAG scoping searches	Das (ERJ, 2021; PA3630)	Abstract	Intervention: ArtiQ PFT (assumed from use of full PFT data) Study design: AI validation
13.	ArtiQ PFT (Clario, assumed from author affiliations)	EAG scoping searches	Das (Eur Resp J, 2023; 220172)	Full publication	Intervention: ArtiQ PFT (assumed from use of full PFT data) Study design: Lab-based AI development and validation
14.	ArtiQ PFT (Clario)	EAG clinical evidence search	Desbordes (Eur Resp Journal, 2023; 2202348)	Research letter	Intervention: full PFT interpretation, results not exclusive to spirometry
15.	ArtiQ PFT (Clario)	EAG clinical evidence search	Elmahy (Eur Resp J, 2024; PA2466)	Abstract	Intervention: ArtiQ PFT Outcomes: not reported exclusively for spirometry
16.	ArtiQ PFT (Clario)	EAG scoping searches	Topalovic (Eur Resp J, 2019; 1801660)	Full publication	Intervention: ArtiQ PFT Population: 50 subjects with complete PFT (diagnosed with asthma, COPD, other obstructive disease, neuromuscular disease, thoracic deformity, IL, pulmonary vascular disease, healthy) Outcomes: not reported for spirometry exclusively
17.	ArtiQ PFT (Clario)	EAG clinical evidence search	Topalovic (Eur Resp J, 2022; 1217)	Abstract	Duplicate: results also reported in Ray et al (2022)
18.	ArtiQ QC (Clario)	EAG clinical evidence search	Cuyvers (Am J Resp Crit Care Med, 2023a; A4065)	Abstract	Population: people diagnosed with asthma Outcomes: reporting quality of spirometry test only
19.	ArtiQ QC (Clario)	EAG clinical evidence search	Cuyvers (Am J Resp Crit Care Med, 2023b; A4064)	Abstract	Population: people diagnosed with COPD Outcomes: reporting quality of spirometry test only

#	Technology	Source	Study	Publication type	Reasons for exclusion
20.	ArtiQ QC (Clario)	EAG clinical evidence search	Cuyvers (Am J Resp Crit Care Med 2024a; A1463)	Abstract	Population: people diagnosed with asthma Outcomes: reporting quality of spirometry test only Study design: home- vs clinic-based spirometry
21.	ArtiQ QC (Clario)	EAG clinical evidence search	Cuyvers (Am J Resp Crit Care Med, 2024b A1462)	Abstract	Population: mixed, diagnosed (COPD, asthma, ILD) and healthy controls Outcomes: no outcomes in scope (single aspect of QC - early termination) Study design: validation of AI element
22.	ArtiQ QC (Clario)	EAG clinical evidence search	Cuyvers (Eur Resp J, 2024c PA3059)	Abstract	Population: people diagnosed with asthma Outcomes: reporting quality of spirometry test only Study design: home- vs clinic-based spirometry
23.	ArtiQ QC (Clario)	EAG clinical evidence search	Mather (Am J Resp Crit Care Med, 2024; A6369)	Abstract	Population: people diagnosed with asthma Outcomes: reporting quality of spirometry test only
24.	ArtiQ QC (Clario)	EAG scoping searches	Stanojevic (Eur Resp J, 2021; OA2688)	Abstract	Population: children with cystic fibrosis and healthy controls
25.	ArtiQ QC (Clario)	EAG clinical evidence search	Topole (ERJ Open Res, 2023; 00292-2022)	Full publication	Population: sample of spirometry data from patients enrolled in Chiesi COPD and asthma trials (people diagnosed with COPD or asthma) Outcomes: reporting quality of spirometry test only Study design: validation of AI
26.	ArtiQ QC (Clario)	EAG scoping searches	Wang (Eur Resp J, 2022; 2200490)	Research letter	Population: healthy non-smokers aged 20 years and older Intervention: spirometry for general health screening, no reported use of diagnostic algorithm Outcomes: reporting quality of spirometry test only
27.	ArtiQ Spiro (Clario)	EAG clinical evidence search	Adams (Eur Resp J, 2024; PA4337)	Abstract	Duplicate: full results reported in Adams (2024)
28.	ArtiQ Spiro (Clario)	EAG scoping searches	Doe (BMJ, 2024a; e086736)	Full publication	Study design: study protocol Outcomes: no outcomes in scope reported
29.	ArtiQ Spiro (Clario)	EAG clinical evidence search	Doe (Eur Res J, 2024b; RCT999)	Abstract	Duplicate: reported in full publication Doe (2025a)
30.	ArtiQ Spiro (Clario)	Company submitted evidence	Hayes (PCRS, 2025a)	Abstract	Duplicate: reported in Hayes (2025b) alongside qualitative outcomes
31.	EasyOne (NDD)	EAG scoping searches	Burton (J Asthma, 2015; 913-919)	Full publication	Population: people with an asthma diagnosis undergoing clinical review Outcomes: reporting quality of spirometry test only
32.	EasyOne Connect (NDD)	EAG scoping searches	Bonthada (Biomed Signal Processing and Control, 2024; 105845)	Full publication	Outcomes: no outcomes in Scope reported Study design: narrative and development of AI summary
33.	EasyOne Diagnostic Spirometer (NDD)	EAG scoping searches	Barr (Respir Care, 2008; 433-441)	Full publication	Population: healthy volunteers Study design: predominantly lab-based validation study
34.	EasyOne Frontline spirometer (NDD)	EAG scoping searches	Thompson (Ped Pulmnolol 2006; 819-828)	Full publication	Population: children diagnosed with asthma Intervention: daily spirometry for monitoring Outcomes: reporting quality of spirometry test only
35.	EasyOne Plus spirometer (NDD)	EAG scoping searches	Gebremariam (BMC Pulmonary Med, 2019; 187)	Full publication	Outcomes: no outcomes in Scope reported
36.	EasyOne Plus spirometer (NDD)	EAG clinical trials search	NCT02566902	Clinical trials registration	Population: children diagnosed with asthma Intervention: use of spirometry before and after nebuliser treatment Outcomes: no outcomes in scope reported
37.	EasyOne Plus spirometer (NDD)	EAG clinical trials search	NCT02061280	Clinical trials registration	Population: children diagnosed with asthma Intervention: use of spirometer for home monitoring Outcomes: reports data collection for QC of test only
38.	EasyOne Pro spirometer (NDD)	EAG scoping searches	Jorres (BMC Pulmonary Med, 2024; 127), Clinical trials registration, NCT04531293	Full publication	Outcomes: no outcomes in Scope reported

#	Technology	Source	Study	Publication type	Reasons for exclusion
39.	EasyOne Pro spirometer (NDD)	EAG clinical trials search	NCT01951833	Clinical trials registration	Population: adults and children with cystic fibrosis Intervention: spirometry for monitoring only Study design: withdrawn study
40.	EasyOne Pro LAB (NDD)	EAG clinical trials search	NCT03320382	Clinical trials registration	Population: mixed, people with one of the following lung conditions: cystic fibrosis, primary ciliary dyskinesia, non-cystic fibrosis bronchiectatis, asthma, persistent bacterial bronchitis, or sleep disordered breathing. Healthy controls. Intervention: EasyOne Pro LAB multiple breath washout device
41.	EasyOne Pro LAB (NDD)	EAG clinical trials search	NCT02368080	Clinical trials registration	Population: adults with cystic fibrosis and healthy controls Intervention: EasyOne Pro LAB multiple breath washout device
42.	EasyOne Pro LAB (NDD)	EAG clinical trials search	NCT02378454	Clinical trials registration	Population: children with cystic fibrosis and healthy paediatric controls Intervention: EasyOne Pro LAB multiple breath washout device
43.	EasyOne Pro LAB (NDD)	EAG scoping search	Oestreich (J Appl Physiol, 2024; 460-471)	Full publication	Population: healthy adults and children, children with cystic fibrosis or primary ciliary dyskinesia Intervention: EasyOne Pro LAB multiple breath washout device Outcomes: no outcomes in Scope reported Study design: algorithm validation, lab-based approach
44.	EasyOne Pro LAB (NDD)	EAG scoping search	Tonga (ERJ open research, 2017; 3)	Full publication	Population: mixed healthy volunteers and patients with asthma (in vivo study, also had in vitro study component) Intervention: multiple breath washout Study design: in vivo and in vitro lab-based study Outcomes: no outcomes in Scope reported
45.	EasyOne Pro LAB (NDD)	EAG scoping search	Zwitserloot (ERJ open research, 2020; 00247-2019)	Full publication	Population: healthy volunteers Intervention: EasyOne Pro LAB multiple breath washout device Study design: in vivo and in vitro lab-based study Outcomes: no outcomes in Scope reported
46.	EasyOne Pro (NDD)	EAG scoping search	Zwitserloot (Respiratory Medicine, 2014; 1254-1259)	Full publication	Population: children diagnosed with asthma Intervention: EasyOne Pro multiple breath washout device Outcomes: no outcomes in Scope reported
47.	EasyOne spirometer (NDD)	EAG scoping searches	Gutwein (Annals of Allergy, 2023; 791-796)	Full publication	Population: people with and without asthma Intervention: spirometry for general health screening Outcomes: no outcomes in Scope reported
48.	EasyOne spirometer (NDD)	EAG clinical evidence searches	Jarhyan (Am J Resp Crit Care Med, 2018; A6171)	Abstract	Population: general population health screening Comparator: between-spirometer comparison
49.	EasyOne spirometer (NDD)	EAG clinical evidence searches	Krishnan (Am J Resp Crit Care, 2020; A6268)	Abstract	Intervention: no report of software quality assessment or interpretation, clinician quality assessment only
50.	EasyOne spirometer (NDD)	EAG scoping searches	Leuppi (Respiration, 2010; 469-474)	Full publication	Population: smokers aged 40 years and older Intervention: spirometry for general health screening, no reported use of diagnostic algorithm Likely overlap with Miedinger (2010, authorship, recruitment setting, results)
51.	EasyOne spirometer (NDD)	EAG scoping searches	Miedinger (Primary Care Respiratory Journal, 2010; 163-169)	Full publication	Population: smokers aged 40 years and older Intervention: spirometry for general health screening, no reported use of diagnostic algorithm Likely overlap with Leuppi (2010, authorship, recruitment setting, results)
52.	EasyOne spirometer (NDD)	EAG scoping searches	Milanzi (Environmental Health, 2019; 39)	Full publication	Population: healthy volunteers Study design: validation of spirometry parameter between two spirometers Outcomes: no outcomes in scope reported
53.	Not in scope	EAG Clinical evidence search	Mundy (Adelaide HTA, 2007)	Full publication	Outcomes: no outcomes in scope reported

#	Technology	Source	Study	Publication type	Reasons for exclusion
54.	EasyOne spirometer (NDD)	EAG scoping searches	Onesmo (BMC Pulmonary Medicine, 2023; 280)	Full publication	Population: small-holder fish vendors Intervention: spirometry for general health screening, no reported use of diagnostic algorithm
55.	EasyOne spirometer (NDD)	EAG scoping searches	Pérez-Padilla (Resp Care, 2006; 1167-1171)	Full publication	Population: general population Intervention: spirometry for general health screening, no reported use of diagnostic algorithm Outcomes: no outcomes in Scope reported
56.	EasyOne spirometer (NDD)	EAG scoping searches	Pérez-Padilla (Resp Care, 2008, 1019-1026)	Full publication	Population: general population Intervention: spirometry for general health screening, no reported use of diagnostic algorithm Outcomes: reporting quality of spirometry test only
57.	EasyOne spirometer (NDD)	EAG scoping searches	Skloot (Resp Care, 2010; 873-877)	Full publication	Population: people undergoing spirometry Study design: calibration accuracy study Outcomes: no outcomes in Scope reported
58.	EasyOne spirometer (NDD)	EAG scoping searches	Tan (J COPD, 2014; 143-151)	Full publication	Population: general population Intervention: spirometry for general health screening, no reported use of diagnostic algorithm Outcomes: reporting quality of spirometry test only
59.	EasyOne spirometer (NDD)	EAG scoping searches	Walters (Respirology 2006, 306-310)	Full publication	Study design: calibration accuracy study Outcomes: no outcomes in Scope reported
60.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Campbell (Resp Thera, 2022; 32-33)	Editorial	Population: people with cystic fibrosis Intervention: home-based spirometry for monitoring Study design: narrative review Outcomes: no outcomes in Scope reported
61.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Carey (RT Magazine, 2020; 16-17)	Magazine article	Intervention: home-based spirometry for asthma monitoring Study design: narrative summary of asthma management pathways during COVID-19 Outcomes: no outcomes in Scope reported
62.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Gupta (Pulmonary Insights, 2020)	Website editorial	Population: people diagnosed with lymphangioleiomyomatosis Intervention: home-based spirometry for monitoring
63.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	McCarthy (Resp Thera, 2017; 38-42)	Editorial	Outcomes: no outcomes in Scope reported
64.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Monitored Therapeutics (ATS, 2024)	Poster	Study design: narrative of features for use of technology for home monitoring and comparison of spirometer performance compared to hospital lab-based spirometry Outcomes: no outcomes in scope reported
65.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Monitored Therapeutics_Doc2 [CIC, no date]	[redacted]	[redacted]
66.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Monitored Therapeutics_Doc3 [CIC, no date]	[redacted]	[redacted]
67.	GoSpiro (Monitored Therapeutics)	EAG clinical evidence search	Podolanczuk (Am J Resp Crit Care Med, 2023; A4978)	Abstract, poster also submitted by Company	Population: people diagnosed with IPF Outcomes: reporting quality of spirometry test only Study design: home- vs clinic-based spirometry
68.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Sheshadri (JMIR Form Res, 2022; e29393)	Full publication	Population: people with allogeneic hematopoietic cell transplantation Intervention: home telemonitoring spirometry to detect lung complications, no reported use of algorithm for diagnosis of asthma, COPD or ILD
69.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Stenzler (Resp Thera, 2017; 32-34)	Editorial	Outcomes: no outcomes in Scope
70.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Stenzler (Resp Thera, 2018; 48-54)	Editorial	Population: patients using home spirometry monitoring (reason or disease not specified) Intervention: GoSpiro for home spirometry monitoring Outcomes: reporting quality of spirometry test only

#	Technology	Source	Study	Publication type	Reasons for exclusion
71.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Stenzler (Resp Thera, 2019a; 18-20)	Editorial	Outcomes: no outcomes in Scope Study design: lab-based comparison of spirometers
72.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Stenzler (Resp Thera, 2019b; 45-47)	Editorial	Population: people diagnosed with COPD Intervention: home spirometry for monitoring Outcomes: reporting quality of spirometry test only
73.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Stenzler (Resp Thera, 2022; 55-58)	Editorial	Outcomes: no outcomes in Scope Study design: comparison of clinical guidelines
74.	GoSpiro (Monitored Therapeutics)	Company submitted evidence	Turner (Transplant Cell Therapy, 2021; 616)	Full publication	Population: people with allogeneic hematopoietic cell transplantation Intervention: home telemonitoring spirometry to detect bronchiolitis obliterans syndrome, no reported use of algorithm for diagnosis of asthma, COPD or ILD
75.	LungHealth (LungHealth Ltd)	EAG clinical evidence search	Angus (Am J Respir Crit Care Med, 2011; A1499)	Abstract	Duplicate: subset of full results reported in Angus (2012)
76.	LungHealth (LungHealth Ltd)	EAG scoping search	Chakrabarti (Prim Care Resp Med, 2023; 6)	Full publication	Population: patients diagnosed with asthma Intervention: undergoing clinical review without spirometry Outcomes: no outcomes in Scope reported
77.	LungHealth (LungHealth Ltd)	EAG scoping search	Chakrabarti (PCRS, 2024)	Poster	Population: patients diagnosed with asthma Intervention: undergoing clinical review without spirometry Outcomes: no outcomes in Scope reported
78.	LungHealth (LungHealth Ltd)	Company submitted evidence	Chakrabarti (PCRS, 2025e; 446)	Presentation slides	Population: people diagnosed with asthma Intervention: undergoing clinical review without spirometry Outcomes: no outcomes in Scope reported
79.	LungHealth (LungHealth Ltd)	Company submitted evidence	Chakrabarti (PCRS, 2025f; 429)	Poster	Population: people diagnosed with asthma Intervention: undergoing clinical review without spirometry Outcomes: no outcomes in Scope reported
80.	LungHealth (LungHealth Ltd)	EAG scoping search	Davies (Am J Resp Crit Care Med, 2012; A3731)	Abstract	Outcomes: results reported in Angus et al. 2012
81.	LungHealth (LungHealth Ltd)	EAG clinical evidence searches	Thompson (Am J Resp Crit Care Med, 2013c; A4379)	Abstract	Duplicate: clinical outcomes reported in Thompson 2013b Study design: narrative review with cost analysis Outcomes: no outcomes in scope reported
82.	MIR Spirobank (MIR)	EAG clinical evidence searches	Bindler (J Asthma, 2023; 1474-1479)	Full publication	Population: people self-diagnosed with asthma Intervention: spirometer used for home monitoring only Outcomes: No outcomes in scope reported
83.	MIR Spirobank (MIR)	EAG scoping searches	Degryse (Resp, 2012: 543-552)	Full publication	Outcomes: no outcomes in Scope reported Study design: inter-comparison comparison of spirometry values between spirometers
84.	MIR Spirobank Smart (MIR)	EAG clinical trials search	NCT05061810	Clinical trials registration	Population: people diagnosed with COPD Intervention: spirometer used for home monitoring only Outcomes: no outcomes in scope reported
85.	MIR Spirobank Smart (MIR)	EAG scoping searches	Lin (Diagnostics, 2021; 785)	Full publication	Intervention: MIR Spirobank Smart, no reported use of algorithm to support test interpretation Outcomes: no outcomes in Scope reported Study design: inter-comparison comparison of spirometry values between spirometers
86.	MIR Spirobank Smart (MIR)	EAG scoping searches	Moor (Am J Respir Crit Care Med, 2020; 393-401)	Full publication	Population: people diagnosed with IPF Intervention: home monitoring programme including daily spirometry, no reported use of algorithm to support interpretation Outcomes: no outcomes in scope reported exclusively for spirometry
87.	MIR Spirobank Smart (MIR)	EAG scoping searches	Wijsenbeek (Adv Ther 2021; 4040-4056)	Full publication	Intervention: home spirometry, no reported use of algorithm to support test interpretation Outcomes: reporting quality of spirometry test only

#	Technology	Source	Study	Publication type	Reasons for exclusion
88.	MIR Spiro Lab II spirometer (MIR)	EAG scoping searches	Shadab (JCDR, 2014; BC11-BC13)	Full publication	Population: sewage workers and healthy controls Intervention: spirometry for general health screening
89.	Mixed	EAG Economic evidence search	Aaron (Am J Resp Crit Care Med, 2024; 928-937)	Full publication	Study design: narrative review (non-systematic). [Noted mention of two papers using spirobank: Lin et al. 2021; Chen et al. 2021 considered in clinical evidence. Also mentioned UK retrospective cohort of CPRD/HES databases: Kostikas et al. 2020 which was considered useful for conceptual economic model development]
90.	Mixed (Easy On PC, NDD, ArtiQ QC)	EAG clinical evidence search	Stanojevic (Am J Resp Crit Care Med, 2024; A2633)	Abstract	Population: general population aging study Study design: comparison of technology algorithms by clinical guidelines
91.	Mixed (EasyOne, Spirobank)	EAG scoping searches	Liistro (COPD, 2006, 657-665)	Full paper	Population: healthy volunteers and people with COPD (different for each centre and apparatus) Study design: lab-based comparison of spirometry values between spirometers Outcomes: no outcomes in Scope reported exclusively for individual technologies
92.	Mixed (EasyOne Air, Spirohome Clinic)	EAG scoping searches	Sekerel (J of Asthma and Allergy, 2022; 219-229)	Full paper	Population: healthy controls and paediatric patients with asthma or allergic rhinitis Study design: comparison of spirometry values between spirometers
93.	Mixed (LungHealth and ArtiQ)	Company submitted evidence	Chakrabarti (ERJ Open Res, 2025c, in press)	Research letter, in press	Population: people aged 40 years and older Intervention: health assessment including blood pressure, BMI, 30 second six-lead ECG, spirometry using ArtiQ, NT-ProBNP, FeNO, and HbA1c and review with Cardio LungHealth software
94.	Mixed (LungHealth and ArtiQ)	Company submitted evidence	Chakrabarti (2025b, AiC)	Presentation slides	Duplicate: full results in Chakrabarti (2025d)
95.	Mixed (MIR Spirobank Smart, Nonin oximeter, patientMpower app)	EAG clinical trials search	NCT05662124	Clinical trials registration	Population: people diagnosed with fibrotic interstitial lung disease Intervention: spirometer for home monitoring Outcomes: no outcomes in scope reported
96.	Mixed (MIR Spirobank Smart, VitalFlo app)	EAG clinical trials search	NCT03705325	Clinical trials registration	Population: people aged between 12 and 21 years diagnosed with asthma Intervention: spirometry for home monitoring only Outcomes: no outcomes in scope reported
97.	Mixed (NuvoAir and ArtiQ QC)	EAG clinical evidence search	Pradhan (Am J Resp Crit Care Med, 2024; A2623), clinical trials registration [NCT05219773]	Abstract	Population: people diagnosed with asthma or COPD Intervention: combination of NuvoAir and over-readings by ArtiQ QC in home monitoring Comparator: home- vs clinic-based spirometric values Outcomes: no outcomes in Scope reported
98.	Mixed (NuvoAir or MIR Spirobank Smart)	EAG clinical evidence search	Barker (Thorax, 2023; P63)	Abstract	Population: children and young people with and without lung conditions Study design: inter-comparison comparison of spirometry values between spirometers Comparator: clinic-based pulmonary function testing
99.	Mixed (NuvoAir, Charge 3 Fitbit, Foobot, smartphone app)	EAG clinical trials search	NCT04373070	Clinical trials registration	Population: people diagnosed with COPD Intervention: use of devices for home monitoring Study design: clinical trials registration without associated publications
100.	Not defined	EAG Economic evidence search	Aiyer (Am J Resp Crit Care Med, 2025; 211)	Abstract	Study design: economic analysis of burden of COPD underdiagnosis. Abstract: lacking sufficient detail in methods
101.	Not in scope	EAG Economic evidence search	Adab (PGAR, 2021)	Full publication	Duplicate: results reported in Lambe et al. 2019.
102.	Not in scope	EAG Economic evidence search	Cadham (BMC Health Services Research, 2025; 385)	Full publication	Intervention: 4 diagnostic strategies (machine learning algorithm, genomic classifier, biopsy all strategy, treat-all strategy)

#	Technology	Source	Study	Publication type	Reasons for exclusion
					[Considered useful for conceptual economic model development]
103.	Not in scope	EAG Economic evidence search	Cadham (Value in Health, 2023; S72)	Abstract	Duplicate: full paper Cadham et al. 2025
104.	Not in scope	EAG Economic evidence search	Cavailles (Int J COPD, 2020; 949-962)	Full publication	Population: patients hospitalised with acute exacerbation of COPD Intervention: None (unclear how diagnosed) Study design: cohort study reporting mortality and hospital care usage of COPD in France.
105.	Not in scope	EAG Economic evidence search	Darba (ClinicoEconomics and Outcomes Research, 2021; 289-297)	Full publication	Intervention: FeNO applied at diagnosis and management Comparator: spirometry (undefined) with reversibility test [Considered useful for conceptual economic model development]
106.	Not in scope	EAG Economic evidence search	Du (Annal Palliative Med, 2021; 4652-4660)	Full publication	Intervention: COPD questionnaire, those above threshold given portable pulmonary function test (Jaeger Pulmonary Function test; not in scope)
107.	Not in scope	EAG Economic evidence search	Duenas-Meza (Ped Pulmonol, 2020; 3110-3118)	Full publication	Intervention: integrated care programme (management) [Considered useful for conceptual economic model development]
108.	Not in scope	EAG Economic evidence search	Hoogendoorn (Value in Health, 2019; 313-321)	Full publication	Intervention: different COPD treatments (pharmacological) [Considered useful for conceptual economic model development]
109.	Not in scope	EAG Economic evidence search	Johnson (Appl Health Eco and Health Policy, 2021; 203-215)	Full publication	Population: population screening Intervention: 16 primary care-based diagnostic strategies using 2 types of case detection (hand-held flow meter, not explicitly mentioning any of the technologies in scope, and COPD diagnostic questionnaire).
110.	Not in scope	EAG Economic evidence search	Johnson (Value in Health, 2020; S352)	Abstract	Duplicate: full paper Johnson et al. 2021
111.	Not in scope	EAG Economic Scoping search	Kostikas (Int J Chron Obstruct Pulmon Dis, 2020; 1729-1738)	Full publication	Population: people diagnosed with COPD Intervention: no specific intervention Study design: comparison of populations with early and late COPD diagnosis [Considered useful for conceptual economic model development]
112.	Not in scope	EAG Economic evidence search	Lambe (Thorax, 2019; 730-739)	Full publication	Intervention: systematic case-finding programme using respiratory screening questionnaire versus routine diagnostic process. [Considered useful for conceptual economic model development]
113.	Not in scope	EAG Economic evidence search	Larsson (Int J COPD, 2021; 701-713)	Full publication	Population: confirmed diagnosis of COPD Intervention: None (physician diagnosed; unclear how diagnosed) Study design: cohort study reporting count of exacerbations in diagnosed population
114.	Note in scope	EAG Economic evidence search	Larsson (Int J COPD, 2019; 995-1008)	Full publication	Population: confirmed diagnosis of COPD Intervention: None (physician diagnosed; unclear how diagnosed) Study design: cohort study reporting differences in outcomes between late and early diagnoses
115.	Not in scope	EAG Economic evidence search	Mountain (CMAJ Open, 2023; E1048-E1058)	Full publication	Population: population screening Intervention: 8 primary-care based case detection strategies (not explicitly mentioning any of the technologies in scope)
116.	Not in scope	EAG Economic evidence search	Nasser (Respir Res, 2021, 62)	Full publication	Population: identification of progressive fibrosing interstitial lung disease (PF-ILD) from healthcare database Intervention: None (unclear how diagnosed) Study design: cohort study reporting mortality and disease burden of PF-ILD

#	Technology	Source	Study	Publication type	Reasons for exclusion
					[Considered useful for conceptual economic model development]
117.	Not in scope	EAG Economic evidence search	Pan (BMJ Open, 2021; 051885)	Full publication	Population: general population screening Intervention: 6 index tests (questionnaires, micro-spirometry using Vitalograph, peak flow)
118.	Not in scope	EAG Economic evidence search	Qu (Pri Care, 2021, 28)	Full publication	Population: screening Intervention: portable spirometer (e-LinkCare PF280; not in scope) and questionnaire [Considered useful for conceptual economic model development]
119.	Not in scope	EAG Economic evidence search	Qu (Value in Health, 2019; S353)	Abstract	Duplicate: full paper considered Qu et al. 2021 Abstract: lacking sufficient detail in methods
120.	Not in scope	EAG Economic evidence search	Ramon (Value in Health, 2022; S158)	Abstract	Study design: two-round delphi panel (28 experts; Spain) to determine costs associated with progressive fibrosing ILD Abstract: lacking sufficient detail in methods
121.	Not in scope	EAG Economic evidence search	Wong (Am J Respir Crit Care Med, 2023; D102)	Abstract	Study design: mapping EQ-5D to FVC and diffusing capacity for ILD Abstract: lacking sufficient detail in methods and results
122.	Not in scope	EAG Economic evidence search	Yaghoubi (J Allerg Clin Immunol, 2020; 1367-1377)	Full publication	Intervention: stepwise objective diagnostic verification algorithm (spirometry with reversibility testing before and after inhaled bronchodilation; not mention of technologies listed in Final Scope) [Considered useful for conceptual economic model development]
123.	Not in scope	EAG Economic evidence search	Yakutcan (BMJ Open, 2022; e062305)	Full publication	Intervention: computer-based decision support tool (not listed in Final Scope) to measure impact of COVID-19 on COPD management
124.	Not in scope	EAG Economic evidence search	Yang (Arch Dis Child, 2022; 21-25)	Full publication	Intervention: use of portable spirometry (technology not defined) and FeNO Population: combined diagnosed and suspected asthma undergoing clinical review Study design: aim to determine training costs and healthcare use and utilities before and after training.
125.	Not in scope	EAG Economic Scoping search	Zafari (J Allergy Clin Immunol, 2014; 908-915)	Full publication	Population: people diagnosed with uncontrolled asthma Intervention: no intervention in scope, adherence to controller medications [Considered useful for conceptual economic model development]
126.	Not in scope	EAG Economic Scoping search	Zafari (Value in Health, 2017; 152-162)	Full publication	Population: people diagnosed with COPD Study design: systematic review of simulation models of COPD [Considered useful for conceptual economic model development]
127.	NuvoAir (NuvoAir)	EAG clinical evidence search	Agerskov (Am J Resp Crit Care Med, 2021; A1088)	Abstract	Population: children diagnosed with asthma Outcomes: reporting quality of spirometry test only
128.	NuvoAir (NuvoAir)	EAG clinical evidence search	Althobiani (Eur Resp J, 2022a; 1756)	Abstract	Population: people diagnosed with ILD Outcomes: no outcomes in Scope reported
129.	NuvoAir (NuvoAir)	EAG clinical evidence search	Althobiani (Thorax, 2022b; S120)	Abstract	Population: people diagnosed with ILD Outcomes: reporting quality of spirometry test and adherence only
130.	NuvoAir (NuvoAir)	EAG clinical evidence search	Althobiani (Eur Resp J, 2023; PA1588)	Abstract	Population: people diagnosed with COPD Outcomes: reporting quality of spirometry test only
131.	NuvoAir (NuvoAir)	EAG clinical evidence search	Boyd (Am J Resp Crit Care Med, 2022; A2787)	Abstract	Population: people diagnosed with COPD Outcomes: reporting quality of spirometry test only, user feedback relating to monitoring aspects only
132.	NuvoAir (NuvoAir)	EAG clinical evidence search	Chen (Thorax, 2022; P88)	Abstract	Population: children diagnosed with asthma Outcomes: reporting quality of spirometry test only

#	Technology	Source	Study	Publication type	Reasons for exclusion
					Study design: comparison of home- vs clinic-based spirometry
133.	NuvoAir (NuvoAir)	EAG clinical evidence search	Clarke (Thorax, 2023; M30)	Abstract	Population: people diagnosed with asthma Intervention: NuvoAir and pathway redesign for asthma management and monitoring Outcomes: no outcomes in scope reported
134.	NuvoAir (NuvoAir)	Company submitted evidence	Du Plessis (S Afr Med J, 2019; 219-222)	Full publication	Population: people with lung diseases (COPD, post-tuberculousis structural lung disease, bronchiectasis, lung masses, sarcoidosis, tuberculousis, ILD, pulmonary hypertension, pleural effusions, pneumoconiosis, previous neumonectomy) or healthy volunteers Study design: validation study comparing home- and clinic-based spirometers
135.	NuvoAir (NuvoAir)	Company submitted evidence	Exarchos (Eur Resp J, 2019; PA2642)	Abstract	Population: people diagnosed with asthma, COPD or ILD and healthy controls Study design: concordance of spirometer values between spirometers
136.	NuvoAir (NuvoAir)	EAG scoping search	Exarchos (Respir Res, 2020; 79)	Full publication	Population: people with known lung conditions and healthy individuals Outcomes: no outcomes in Scope reported
137.	NuvoAir (NuvoAir)	Company submitted evidence	Exarchos (Eur Resp J, 2021; PA3442)	Abstract	Study design: validation of algorithm study
138.	NuvoAir (NuvoAir)	Company submitted evidence	Gogali (Eur Resp J, 2020; 166)	Abstract	Population: people diagnosed with asthma Outcomes: reporting quality of spirometry test only
139.	NuvoAir (NuvoAir)	Company submitted evidence	Hawkes (J Cystic Fibrosis, 2021; S227)	Abstract	Population: people diagnosed with cystic fibrosis Intervention: remote monitoring including home-based spirometry
140.	NuvoAir (NuvoAir)	EAG clinical trials search	ISRCTN 14101933	Clinical trials registration	Outcomes: no outcomes available; study terminated prior to recruitment due to funding
141.	NuvoAir (NuvoAir)	EAG clinical evidence search	Kostikas (Am J Resp Crit Care Med, 2021; A4536)	Abstract	Population: people diagnosed with asthma Outcomes: reporting quality of spirometry test only
142.	NuvoAir (NuvoAir)	EAG clinical evidence search	Lewis (Eur Resp J, 2024, OA1050)	Abstract	Population: people diagnosed with COPD Outcomes: reporting quality of spirometry test only
143.	NuvoAir (NuvoAir)	EAG clinical evidence search	Matthes (Eur Resp J, 2024; PA5189)	Abstract	Population: people diagnosed with asthma or COPD Intervention: NuvoAir spirometer, SpO2 and app (for monitoring) Outcomes: no outcomes in Scope reported (usability and satisfaction not exclusively for spirometry)
144.	NuvoAir (NuvoAir)	EAG clinical evidence search	Nichols (Arch Dis Child, 2022; e15)	Full publication	Population: children diagnosed with asthma Outcomes: reporting quality of spirometry test only
145.	NuvoAir (NuvoAir)	EAG clinical evidence search	Potonos (Pneumon, 2023; 32)	Full publication	Population: people diagnosed with asthma Outcomes: reporting quality of spirometry test only
146.	NuvoAir (NuvoAir)	EAG clinical evidence search	Raywood (Thorax, 2023; P236)	Abstract	Population: people diagnosed with COPD Outcomes: reporting quality of spirometry test only, user feedback relating to monitoring aspects only
147.	NuvoAir (NuvoAir)	Company submitted evidence	Robshaw (Inspire, 2023; P14)	Abstract	Population: people diagnosed with asthma Outcomes: reporting quality of spirometry test only
148.	NuvoAir (NuvoAir)	EAG clinical evidence search	Roy (Eur Resp J, 2024; PA3952)	Abstract	Population: people diagnosed with asthma Outcomes: reporting quality of spirometry test only
149.	NuvoAir (NuvoAir)	EAG scoping searches	Thyagarajan (AACR 2020; 744-751)	Full publication	Population: general population Intervention: spirometry for general health screening, no reported use of diagnostic algorithm Outcomes: no outcomes in Scope reported

Appendix B – Economic modelling

Appendix B1: Summary of economic papers used to support development of a conceptual economic model

#	Study (year)	Country	Population [details]	Study description	Key results	Information useful to development of conceptual model
1.	Darba (ClinicoEconomics and Outcomes Research, 2021; 289-297)	Sweden	Asthma [General population]	Economic model (undefined: assumed decision tree). The aim of the study was to evaluate introduction of FeNO into diagnosis and management of asthma in primary care (spirometry as a comparator). Analysis from Swedish healthcare payer perspective, reported in Swedish crowns [SEK] from 2019 price year.	Results were sensitive to asthma prevalence, cost of standard tests, and FeNO costs.	Separation of severity of exacerbation (moderate and severe), range of asthma prevalence used in sensitivity analysis.
2.	Duenas-Meza (Ped Pulmonol, 2020; 3110-3118)	Colombia	Asthma [Paediatric, already diagnosed]	Markov model. Time horizon of 15 years, with 2-week cycles. Costs reported in Colombian pesos [COP] and US dollars, EAG have assumed 2017 price year.	Integrated care programme is considered cost effective when compared with standard of care. The economic model results were sensitive to costs of care (with and without integrated care plan), and cost of severe exacerbation.	Markov model states including controlled asthma, severe exacerbation (hospitalisation required), non-severe exacerbation, death.
3.	Cadham (BMC Health Services Research, 2025; 385)	US	Restrictive lung disease (IPF). [Patients with chronic lung disease with probable-to-indeterminate usual interstitial pneumonia patterns based on chest CT, where MDT had residual uncertainty about the diagnostic subtype (such as IPF, hypersensitivity pneumonitis) before use of invasive procedure]	Decision analytical model (CEA) comparing 4 diagnostic strategies (machine learning algorithm, genomic classifier, biopsy-all strategy, treat-all strategy). Conducted from healthcare perspective, reported in US dollars using 2022 price year, Monte Carlo simulation with a lifetime horizon.	Machine-learning algorithm (FibreSolve, which analyses 3D CT scans; not in scope) consistently reduced diagnostic costs. Machine learning algorithm had an ICER of $331,069 per QALY when compared to biopsy-all strategy. Results sensitive to changes in IPF treatment costs, sensitivity and specificity of screening tools, rate of additional diagnostics following inconclusive results. High treatment costs contributed to overall costs regardless of diagnostic method (as treatment costs lowered, diagnostic tools became increasingly cost-effective).	Decision tree structure for IPF population. Analysis of spirometry (or other pulmonary function tests) were not considered within the 4 diagnostic strategies.
4.	Hoogendoorn (Value in Health, 2019; 313-321)	UK	COPD [Adults diagnosed with COPD, 14 characteristics included in the conceptual model]	Patient-level conceptual model based on discrete event simulation. The model included 7 intermediate outcomes (lung function, physical activity, exercise capacity, symptoms, disease-specific QoL, exacerbations and pneumonia) and 3 outcomes (mortality, QALYs, costs). Lifetime horizon, costs from UK healthcare perspective; reported in GBP, 2015 price year.	Model provided a base case analysis of treatment with tiotropium for which COPD strategies could be compared, with: • Mean lung function decline of 43 ml/year • 0.62 exacerbations/year • Worsening physical activity: 1.48 points/year • Worsening of QoL of 1.10 points/year • Life expectancy of 11.2 years • Total 7.25 QALYs, and total costs of £24,891	Costs (treatment, maintenance, exacerbation related) from UK perspective, subgroup analysis (GOLD, sex, age, smoking, prior LABA/LAMA use, prior ICS use, oxygen use, chronic bronchitis, BMI, activity level, prior antibiotics/steroids/exacerbations, race, region, reversibility). Base case results will support validation of the conceptual model built.
5.	Kostikas (Int J Chron Obstruct Pulmon Dis, 2020; 1729-1738)	UK	COPD [Newly diagnosed from UK Clinical Practice Research Database between 2011	Retrospective cohort of primary care centres.	33% (3,375/10,158) of patients identified with COPD were diagnosed within 5 years of their first presentation (with less than 3 counts of eight indicators of COPD; defined as “early diagnosis”).	Value proposition associated with early detection. Outcomes of interest in COPD population (exacerbations, hospitalisation)

#	Study (year)	Country	Population [details]	Study description	Key results	Information useful to development of conceptual model
			and 2014 (available data 5 years before and 1 after first diagnosis), aged 40 years and older, linked to Hospital Episode Statistics, patients with COPD and asthma were excluded]		Key results: • Early diagnosis group had longer median time to first exacerbation (29.0 [27.4-30.7] months versus 14.5 [13.8,15.1] months; p<0.0001). • Late diagnosis group had higher risk of first exacerbation (HR 1.46 [95%CI 1.38 to 1.55]; p<0.001). • Early diagnosis group has decreased exacerbation rates (57.2 vs. 108.9 exacerbations/100 person-years) at 3 years follow-up [adjusted rate ratio: 1.68 [1.58-1.79]), • Late diagnosis group had increased rate of COPD-related hospitalisations at 2 years (adjusted RR: 1.12 [1.02-1.23]) and 3 years (adjusted rate ratio: 1.18 [1.08-1.28]) follow-up. Similar clinic visits (adjusted rate ratio: 1.03 [1.00-1.06]) and A&E visits (1.19 [1.00-1.42]) between groups at 3 years were observed. Patients who were adherent to medication were less likely to have an exacerbation.	and different event rates by level of adherence to medication. ICD-10 code for COPD exacerbation: J44.0, J44.1, J44.9 in HES APC. Diagnosis code recorded in A&E: 252 respiratory conditions – other non-asthma.
6.	Lambe (Thorax, 2019; 730-739) [Also reported in Adab (PGAR, 2021)]	UK	COPD [Ever smokers, aged 50 years or older, without prior diagnosis of COPD]	Decision analytic model (Markov model) Health service perspective (UK NHS), 2015 price year, 50-year time-horizon, 3-month cycle duration.	Systematic case-finding was reported to be cost-effective (£16,596/QALY), with 78% probability of cost-effectiveness at £20,000/QALY. Key drivers were response rate to the screening questionnaire and attendance rate for confirmatory spirometry test.	Consideration of Markov model structure (no COPD, undiagnosed and diagnosed), split by severity. Only severe exacerbations requiring inpatient stay were included in modelling (authors acknowledge that this contributes to 84% of all COPD-related healthcare costs), averaged effect of treatment on exacerbations and mortality. Table of COPD-adjusted all-cause mortality by age and sex (in Supplementary material). Costs from UK, baseline utilities and decrements from events. Pathway diagram for COPD. Sensitivity analysis applied (age, screening interval, time horizon, spirometry attendance rate, questionnaire response rate, utility gain from treatment).
7.	Nasser (Respir Res, 2021, 62)	France	Restrictive lung disease (patients with progressive fibrosing ILD) [Aged 20 years or older, identified from healthcare database as having progressive fibrosing interstitial lung disease using 3 approaches using frequency of claims]	Retrospective cohort (using French Healthcare national database to identify cohort, authors confirmed absence of high-resolution CT and pulmonary function tests). Costs from national health insurance perspective, reported in Euros (price year not reported).	95.2% (13,727 of 14,413) patients had at least one hospitalisation during follow-up, with median [IQR] annual rate of 3.9 [1.7-9.5]. Of these 11% were hospitalised for pulmonary hypertension, 34.3% were in an ICU.	Baseline characteristics of population with progressive fibrosing interstitial lung disease, estimated prevalence, overall survival from start of progression hospital care utilisation.
8.	Qu (Pri Care, 2021, 28)	China	COPD [Chronic bronchitis patients considered high-risk of COPD]	Decision analytic model (decision tree into a Markov model).	Portable spirometer screening was cost saving when compared to questionnaire screening (£5,026/QALY) and no screening (£1,766/QALY). Key drivers from one-way sensitivity analysis were height of male	Model structure, split by severity (mild, moderate, severe COPD). Exacerbations and pneumonia captured as separate states.

#	Study (year)	Country	Population [details]	Study description	Key results	Information useful to development of conceptual model
				Lifetime horizon with monthly cycle. Costs from healthcare system payer perspective, shown in Chinese Yuan, 2018 price year.	patients, lung volume decline rate, discount rate of costs, and cost of chronic bronchitis treatment.	
9.	Yaghoubi (J Allerg Clin Immunol, 2020; 1367-1377)	US	Asthma [Adults (aged 15 years and older), self-reported physician-diagnosed asthma]	Economic model (decision tree into a Markov model). The aim of the study was to determine the cost-effectiveness of diagnostic verification of asthma at routine outpatient follow-up appointments. Time horizon was 20 years, with annual cycles. The analysis adopted a third-party payer's perspective (health maintenance organisation) in the main analysis, and societal perspective in secondary analysis. Costs were reported in US dollars; 2018 price year.	In 10,000 simulated adults, the step-wise algorithm removed the asthma diagnosis in 3,366 patients (resulting in total savings of $36.2m and gain of 4,049 QALYs over 20 years). Univariate sensitivity analysis found that if the proportion of falsely diagnoses cases was 6% or lower, then diagnostic verification was no longer cost-saving. PSA found that 99% of simulations the intervention remained dominant.	This study did not include longer-term adverse events associated with controller medications but modelled the increased risk of acute pneumonia as an adverse event of inhaled corticosteroids in sensitivity analysis. Baseline utilities by age band and sex, utility values for well controlled, partially controlled and uncontrolled asthma.
10.	Zafari (J Allergy Clin Immunol, 2014; 908-915)	US	Asthma [Adults (aged 19 years and older) with uncontrolled asthma]	Markov model. Time horizon of 10 years, weekly cycles. Costs reported as US dollars, adjusted to 2011 price year.	At the end of 10 years: higher proportion of patients were alive in the full adherence scenario than standard care scenario (74% compared with 62%), the number of weeks with uncontrolled asthma reduced by 31% and the number of exacerbations reduced by 40%. Full adherence associated with $3,187 more costs ($5,973 compared with $2,786), 2.26 fewer exacerbations (2.94 compared with 5.20) and 0.13 more QALYs (7.68 compared with 7.55), resulting in ICER of $24,515/QALY. Probability of being cost-effective at $50,000/QALY was 0.90. Hypothetical program aimed at improving adherence, each $29 increase in annual costs will need to increase adherence level by 10% to remain cost-effective at $50,000/QALY.	Stratified population into 3 age groups (18-35, 36-64 and >64 years). Uncontrolled asthma stratified into 3 groups according to treatment: i) no controller medication, ii) low-dose controller therapy (beclomethasone-equivalent daily dose up to 500 micrograms), iii) medium or high doses controller therapy (beclomethasone-equivalent daily dose of 500-1,000 micrograms).
11.	Zafari (Value in Health, 2017; 152-162)	International (n=21, where reported)	COPD	Systematic review of decision-analytic modelling to project the future burden of COPD for cost-effectiveness analysis of COPD interventions.	49 models of COPD included (including 41 Markov models, 2 decision trees). Time horizon ranged between 6 months and lifetime, and cycle length ranged between 1 week and 1 year. 40 were developed for economic evaluation of COPD treatments or management programmes. 41 studies modelled progression through GOLD grades; only 2 modelled progressions through FEV1 decline. Commonly subgroup analysis included disease severity, sex and age; however, only 8 reported results from subgroup analysis, 2 considered impact of co-morbidities. Treatment effect was commonly modelled through reduction in exacerbation rate without impact on lung function (N=16), with lung function (N=20), and 7 modelled impact on lung function alone. One study modelled treatment effect through reduction in disease mortality and disability.	General modelling approach, structure, assumptions and subgroup analysis approach.

Abbreviations: A&E, accident and emergency; APC, Admitted Patient Care; BMI, body mass index; CEA, cost-effectiveness analysis; CI, confidence interval; COPD, chronic obstructive pulmonary disease; CT, computerised tomography; GBP, Great British Pounds; GOLD, Global Initiative for Chronic Obstructive Lung Disease; HES, Hospital Episode Statistics; HR, hazard ratio; ICD-10, International Classification of Diseases 10th revision; ICS, inhaled corticosteroids; ICU, intensive care unit; ILD, interstitial lung disease; IPF, idiopathic pulmonary fibrosis; IQR, interquartile range; LABA, long-acting beta-2 agonist; LAMA, long-acting muscarinic antagonist; MDT, multidisciplinary team; PSA, probabilistic sensitivity analysis; QALY, quality-adjusted life-year; QoL, quality of life; RR, relative risk

Appendix B2: Model validation

AdViSHE tool

Part A: Validation of the conceptual model (2 questions)

Part A discusses techniques for validating the conceptual model. A conceptual model describes the underlying system (e.g., progression of disease) using a mathematical, logical, verbal, or graphical representation. Please indicate where the conceptual model and its underlying assumptions are described and justified.

Response: Section 6.2

A1/ Face validity testing (conceptual model):

Have experts been asked to judge the appropriateness of the conceptual model? If yes, please provide information on the following aspects: - Who are these experts? - What is your justification for considering them experts? - To what extent do they agree that the conceptual model is appropriate? If no, please indicate why not.
Response: Expert opinion sought on value propositions and key outcomes (NICE Scoping workshop); which were integrated in the decision problem outlined in the scope. Experts sought and ratified by NICE (range of expertise and geographical location across the UK). Model structure and parameters developed based on economic model used in NG245 and NG115 and other published models looking at different self-management technologies. Opinion sought from experts (documented in Appendix D).

A2/ Cross validity testing (conceptual model):

Has this model been compared to other conceptual models found in the literature or clinical textbooks? If yes, please indicate where this comparison is reported. If no, please indicate why not.
Response: For conceptual model the EAG focused efforts on internal validation. Cross checks with other published models are outlined in the following table

	Cohort	Result from EAG conceptual model	Result from published model [source]	Comment
Total cost per patient	Asthma (adult)	£896 comparator @ 20 year time horizon	Between £1355 and £1462 @ life time horizon across	Longer time horizon in NG245, also NG245 includes

			strategies [NG245]	remission (higher utility)
Total QALY per patient	Asthma (adult	11.5 @ 20 year time horizon	Between 18.97 and 19.02 @ life time horizon [NG245]	
Total cost per patient	Asthma (adult)	£593 comparator @ 10 year time horizon	$2,786 @ 10 years [Zafari et al. 2014]	Zafari et al. 2014 applied weighted average of 3 age groups, and uncontrolled stratified into 3 groups according to treatment (US dollars, 2011 price year)
Total QALY per patient	Asthma (adult	6.83 @ 10 year time horizon	7.55 @ 10 years [Zafari et al. 2014]	
Total cost per patient	COPD	£1,188 @ 20 year time horizon	£27,875 @ lifetime time horizon for LAMA+LABA [NG115]	NG115 longer time horizon (mortality and adverse events excluded)
Total QALY per patient	COPD	9.88 @ 20 year time horizon	5.59 @ lifetime time horizon for LAMA+LABA [NG115]	
Total cost per patient	COPD	£1,188 @ 20 year time horizon	£1007@ lifetime time horizon [Lambe et al. 2019]	Lambe et al. 2019 modelled only severe exacerbations, and included progression between GOLD states
Total QALY per patient	COPD	9.88 @ 20 year time horizon	14.17 @ lifetime time horizon [Lambe et al. 2019]	

Part B: Input data validation (2 questions)

Part B discusses techniques to validate the data serving as input in the model. These techniques are applicable to all types of models commonly used in HE modelling. Please indicate where the description and justification of the following aspects are given:

- search strategy;
- data sources, including descriptive statistics;
- reasons for inclusion of these data sources;
- reasons for exclusion of other available data sources;

- assumptions that have been made to assign values to parameters for which no data was available;
- distributions and parameters to represent uncertainty;
- data adjustments: mathematical transformations (e.g., logarithms, squares); treatment of outliers; treatment of missing data; data synthesis (indirect treatment comparison, network meta-analysis); calibration; etc.

B1/ Face validity testing (input data):

Have experts been asked to judge the appropriateness of the input data? If yes, please provide information on the following aspects: - Who are these experts? - What is your justification for considering them experts? - To what extent do they agree that the conceptual model is appropriate? If no, please indicate why not.
Response: Opinion sought from experts on key parameters where data were not available from the clinical evidence (documented in Appendix D).

B2/ Model fit testing:

When input parameters are based on regression models, have statistical tests been performed? If yes, please indicate where the description, the justification and the outcomes of these tests are reported. If no, please indicate why not.
Response: No regression models were directly applied by the EAG during development. Due to lack of clinical evidence, parameterisation based on values used in NG245 and other published economic models (see section 6.2.3, 6.2.4, 6.2.5)

Part C: Validation of the computerized model (4 questions)

C1/ External Review:

Has the computerized model been examined by modelling experts? If yes, please provide information on the following aspects: - Who are these experts? - What is your justification for considering them experts? - To what extent do they agree that the conceptual model is appropriate? If no, please indicate why not.
Response: Model was reviewed by Professor Luke Vale (LV), Professor of Health Economics and an expert in economic evaluation and health technology assessment. The model structure was reviewed as during development and revisions were made to structure and possible transitions. The model appears consistent with existing models in the field, including those used to inform existing NICE guidelines. Estimation and consideration of costs, utilities and transition probabilities seem reasonable. As the focus was on the identification of key uncertainties the sensitivity analyses conducted was appropriate.
Aspects to judge include: appropriateness to represent the underlying clinical process/disease (disease stages, physiological processes, etc.); and

appropriateness for economic evaluation (comparators, perspective, costs covered, etc.).

C2/ Extreme value testing:

Has the model been run for specific, extreme sets of parameter values in order to detect any coding errors? If yes, please indicate where these tests and their outcomes are reported. If no, please indicate why not.
Extreme value testing was performed across parameters used in the decision tree and Markov model. The following tests have been performed: Varied cost of spirometry (increase by cost of technology, cost of spirometry double that of SoC, spirometry cost of £0) Time horizon of 1 and 10 years Sensitivity of spirometry compared at 37% to 47% Specificity of spirometry tested from 76% to 96% (adjusting specificity only) Sensitivity and specificity of spirometry tested at 0 and 1 (for both) Starting age of 64 and 74 Increased proportion of male patients in starting population (50% compared to 34%) Prevalence of disease at 59%, 20%, and 0% All patients receiving testing within 6 months (compared to 63.2%) Shorter testing window (63.2% of patients tested within 1 month compared to within 6 months) 100% of patients had testing within 1 day (and spirometry was available to 100% of patients) Apply utility decrement of 0.01 to false positive diagnoses Applied equivalent utilities across Controlled, Partially Controlled, and Uncontrolled states 100% or 0% of patients given an inhaler while awaiting testing No transitions between Controlled, Partially Controlled, and Uncontrolled states Double or no monitoring costs Double or no cost of exacerbation No utility multiplier (decreasing utility) associated with exacerbation All transitions from exacerbation are back to the Controlled state No mortality associated with disease states (including exacerbation) Extremely high mortality associated with disease (exacerbation and non-exacerbation) Partially Controlled state removed 10% of No Disease cases retested (0% in base case) No change in mortality associated with exacerbation All false positive diagnoses stop treatment In the base case the EAG noted that the transition probability matrix for the COPD model showed a greater probability of moving from the uncontrolled disease state to death, than from the exacerbation state to death. Based on the input parameters used (where the hazard ratio for death from the exacerbation state was higher), this was unexpected. This was explored further in sensitivity analysis, and the EAG noted that the model behaved as

expected when the hazard ratio of death from the exacerbation state was increased to 10. When compared to the base case, the EAG noted a negligible change in the occupancy of the death state at the end of the time horizon, and also in the ICER. Therefore, no further changes were made to account for this, and because similar behaviour was not noted in the asthma models, it was assumed to be related to the large increase in the hazard ratio between the partially controlled and uncontrolled states, and subsequent smaller increase in the hazard ratio between the uncontrolled and exacerbation states. The model also rebalances transition probabilities automatically when it runs, to account for multistep transitions, and this is known to be more accurate for shorter cycle lengths, so the monthly cycle length may have also influenced the behaviour noted.

C3/ Testing of traces:

Have patients been tracked through the model to determine whether its logic is correct? If yes, please indicate where these tests and their outcomes are reported. If no, please indicate why not.
Response: State occupancy through all states for each cycle across the time horizon reviewed by 2 modellers (RO/KK), QA'd by lead health economist (LV) to ensure cohort moving as expected. Extreme testing reviewed (0%, 100%) to ensure cohort movement as expected also. Tabular output and figure illustrating state occupancy over time included in report Appendix B4.

C4/ Unit testing:

Have individual sub-modules of the computerized model been tested? If yes, please provide information on the following aspects: - Was a protocol that describes the tests, criteria, and acceptance norms defined beforehand? - Please indicate where these tests and their outcomes are reported. If no, please indicate why not.
Response: Decision tree within "Testing" state was calculated manually for set values of sensitivity and specificity (SG) to ensure that the subgroup reaching terminal nodes was as expected. However note that '*rdecision*' includes over 1300 internal validation checks. Output reviewed for "warning" (RO/SG).

Part D: Operational validation (4 questions)

Part D discusses techniques used to validate the model outcomes.

D1/ Face validity testing (model outcomes):

Have experts been asked to judge the appropriateness of the model outcomes? If yes, please provide information on the following aspects: - Who are these experts? - What is your justification for considering them experts? - To what extent did they conclude that the model outcomes are reasonable?

If no, please indicate why not.
Response: Draft report with initial results (including end state occupancy, QALY, costs) shared with NICE and SCMs (01/10/2025; 07/10/2025).

D2/ Cross validation testing (model outcomes):

Have the model outcomes been compared to the outcomes of other models that address similar problems? If yes, please provide information on the following aspects: - Are these comparisons based on published outcomes only, or did you have access to the alternative model? - Can the differences in outcomes between your model and other models be explained? - Please indicate where this comparison is reported, including a discussion of the comparability with your model. If no, please indicate why not.
Response: Development of conceptual model focused on internal validation. Due to lack of published clinical evidence full parameterisation was not possible, therefore multiple assumed values used. The model was designed and run to demonstrate key uncertainties and highlight missing data. Therefore, comparing results with other published economic models not considered appropriate. Results of this modelling should be interpreted with caution.

D3/ Validation against outcomes using alternative input data:

Have the model outcomes been compared to the outcomes obtained when using alternative input data? If yes, please indicate where these tests and their outcomes are reported. If no, please indicate why not.
Alternative input data can be obtained by using different literature sources or datasets, but can also be constructed by splitting the original data set in two parts, and using one part to calculate the model outcomes and the other part to validate against.

D4/ Validation against empirical data:

Have the model outcomes been compared to empirical data? If yes, please provide information on the following aspects: - Are these comparisons based on summary statistics, or patient-level datasets? - Have you been able to explain any difference between the model outcomes and empirical data? - Please indicate where this comparison is reported. If no, please indicate why not. **D4.A/** Comparison against the data sources on which the model is based (dependent validation).
Response:
D4.B/ Comparison against a data source that was not used to build the model (independent validation).
Response:

Part E: Other validation techniques (1 question)

E1/ Other validation techniques:

Have any other validation techniques been performed? If yes, indicate where the application and outcomes are reported, or else provide a short summary here.
Response: As part of external validation, the EAG checked the per patient cost associated with the comparator (standard care) which was micro-costed by the EAG (£39.62), against the total cost associated with bronchodilator reversibility used in the NG245 which was published in 2024 (£39.16); concluding these were consistent.
Examples of other validation techniques: structured “walk-throughs” (guiding others through the conceptual model or computerized program step-by-step); naive benchmarking (“back-of-the-envelope” calculations); heterogeneity tests; double programming (two model developers program components independently and/or the model is programmed in two different software packages to determine if the same results are obtained).

Appendix B3: Output from base case: Asthma (adults)

Comparator (SoC) base case

Diagnostic outcome

-	TP	TN	FN	FP
Probability	0.5487	0.3409	0.04128	0.06914

Transition probabilities, age=30 years

-	Undiagnosed	Undiagnosed Treated	Testing	Disease Untreated	Controlled	Partially Controlled	Uncontrolled	Exacerbation	NoDisease	NoDisease Treated	Dead
Undiagnosed	0.8313	0.01751	0.1482	0	0	0	0	0.002882	0	0	4.718e-05
UndiagnosedTreated	0	0.849	0.1482	0	0	0	0	0.002748	0	0	4.717e-05
Testing	0	0	0	0.04102	0.1157	0.2129	0.2194	0	0.3416	0.0693	0
DiseaseUntreated	0	0	0	0.9945	0	0	0	0.005447	0	0	5.556e-05
Controlled	0	0	0	0	0.9463	0.04358	0.004892	0.005134	0	0	5.492e-05
PartiallyControlled	0	0	0	0	0.04167	0.948	0.004997	0.005254	0	0	5.492e-05
Uncontrolled	0	0	0	0	0.00447	0.006533	0.9836	0.005383	0	0	5.492e-05
Exacerbation	0	0	0	0	0.2013	0.366	0.3781	0.05445	0	0	5.579e-05
NoDisease	0	0	0	0	0	0	0	0	1	0	4.393e-05
NoDiseaseTreated	0	0	0	0	0	0	0	0	0	1	4.393e-05
Dead	0	0	0	0	0	0	0	0	0	0	1

Intervention base case

Diagnostic outcome

-	TP	TN	FN	FP
Probability	0.5505	0.3409	0.03953	0.06914

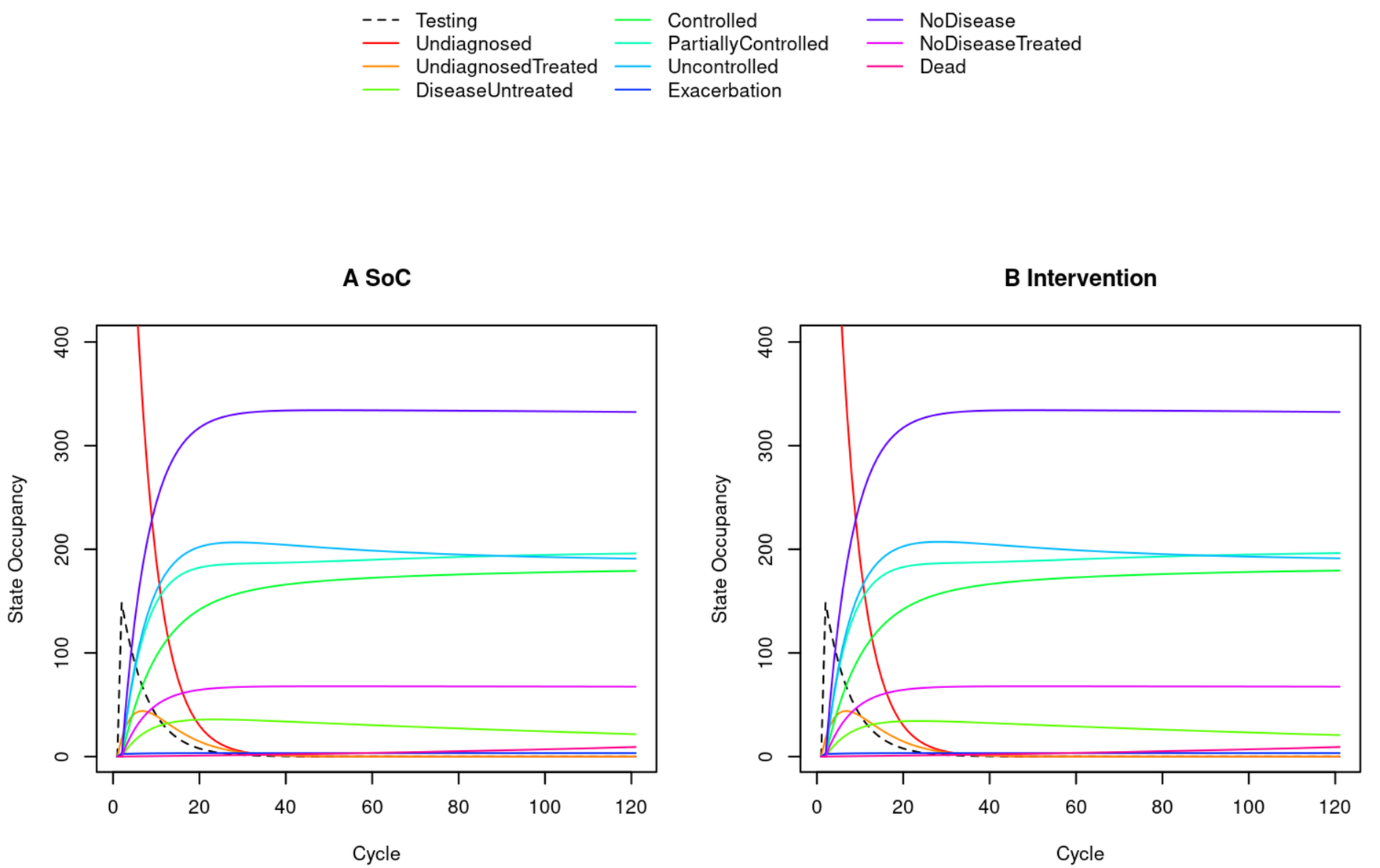
No change in diagnostic outcomes (same sensitivity and specificity modelled in base case).

Transition probabilities, age=30 years

-	Undiagnosed	Undiagnosed Treated	Testing	Disease Untreated	Controlled	Partially Controlled	Uncontrolled	Exacerbation	NoDisease	NoDisease Treated	Dead
Undiagnosed	0.8313	0.01751	0.1482	0	0	0	0	0.002882	0	0	4.718e-05
UndiagnosedTreated	0	0.849	0.1482	0	0	0	0	0.002748	0	0	4.717e-05
Testing	0	0	0	0.03928	0.1161	0.2136	0.2201	0	0.3416	0.0693	0
DiseaseUntreated	0	0	0	0.9945	0	0	0	0.005447	0	0	5.556e-05
Controlled	0	0	0	0	0.9463	0.04358	0.004892	0.005134	0	0	5.492e-05
PartiallyControlled	0	0	0	0	0.04167	0.948	0.004997	0.005254	0	0	5.492e-05
Uncontrolled	0	0	0	0	0.00447	0.006533	0.9836	0.005383	0	0	5.492e-05
Exacerbation	0	0	0	0	0.2013	0.366	0.3781	0.05445	0	0	5.579e-05
NoDisease	0	0	0	0	0	0	0	0	1	0	4.393e-05
NoDiseaseTreated	0	0	0	0	0	0	0	0	0	1	4.393e-05
Dead	0	0	0	0	0	0	0	0	0	0	1

State occupancy (per cycle)

Plot A displays the state occupancies for the comparator (SoC), and plot B displays the state occupancies for the intervention. Note that the y-axis has been limited for visualisation purposes. At cycle 0, the Undiagnosed state had an occupancy of 1000 patients. In the base case the EAG assumed the same objective testing rate for both arms, with the intervention arm having 10% higher diagnostic sensitivity which resulted in few changes to number of patients in each state and the end of the cycle; which explains minimal difference between the graphs between intervention and comparator arms.



Appendix B4: Results from sensitivity analysis

Asthma (adults)

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Comparator	199.30	NA	538.1	334.3	40.48	67.81	2.35e-07	2.667e-06	21.57	67.44	179.1	196	191	3.273	9.222	593.30	6.829	NA	NA	NA	NA
Intervention (LungHealth costs,) + 47% sensitivity	204.10	4.83	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	598.70	6.829	5.406	0.0004393	12,307	3.379
Intervention + 70% objective testing	207.90	8.65	539.9	335.4	40.62	68.04	4.533e-09	5.145e-08	21.52	67.66	178.8	195.6	190.4	3.266	9.219	604.80	6.831	11.5	0.002771	4,152	43.91
Intervention + 80% objective testing	207.90	8.65	542.2	336.8	40.79	68.32	1.776e-12	2.017e-11	21.46	67.94	178.3	195.1	189.8	3.257	9.215	609	6.835	15.7	0.006455	2,433	113.4
Intervention + 90% objective testing	207.90	8.65	544.2	338.1	40.94	68.58	2.595e-18	2.951e-17	21.4	68.19	177.9	194.6	189.2	3.248	9.211	613.10	6.839	19.75	0.01002	1,972	180.6
Intervention +100% objective testing	207.90	8.65	546.6	339.6	41.12	68.88	8.756e-38	9.984e-37	21.34	68.48	177.4	194.1	188.6	3.239	9.206	618.10	6.843	24.77	0.01447	1,712	264.6
Intervention + 42% sensitivity	206.00	6.74	539	334.3	39.62	67.81	2.35e-07	2.667e-06	21.11	67.43	179.3	196.1	191.1	3.273	9.222	600.20	6.829	6.871	0.0002196	31,284	-2.478
Intervention + 57% sensitivity	200.30	1.00	541.6	334.3	37.05	67.81	2.35e-07	2.667e-06	19.74	67.43	179.7	196.6	191.5	3.273	9.221	595.80	6.83	2.477	0.0008786	2,819	15.1
Intervention + 67% sensitivity	196.40	-2.83	543.3	334.3	35.33	67.81	2.35e-07	2.667e-06	18.83	67.43	180	196.9	191.8	3.273	9.221	592.90	6.83	-0.4531	0.001318	Dominant	26.81
Intervention + 77% sensitivity	192.60	-6.65	545	334.3	33.61	67.81	2.35e-07	2.667e-06	17.91	67.43	180.3	197.2	192.1	3.272	9.221	590	6.83	-3.383	0.001757	Dominant	38.53
Intervention + 87% sensitivity	188.80	-10.48	546.7	334.3	31.89	67.81	2.35e-07	2.667e-06	16.99	67.43	180.6	197.6	192.4	3.272	9.221	587	6.831	-6.313	0.002196	Dominant	50.24
Intervention + 94% specificity	203.60	4.30	539.9	332	38.76	70.09	2.35e-07	2.667e-06	20.66	69.7	179.4	196.3	191.2	3.273	9.221	599.60	6.829	6.241	0.0004393	14,207	2.545
Intervention + 91% specificity	202.80	3.50	539.9	328.6	38.76	73.51	2.35e-07	2.667e-06	20.66	73.11	179.4	196.3	191.2	3.273	9.221	600.80	6.829	7.493	0.0004393	17,057	1.293
Intervention + 86% specificity	201.40	2.17	539.9	322.9	38.76	79.22	2.35e-07	2.667e-06	20.66	78.78	179.4	196.3	191.2	3.273	9.221	602.90	6.829	9.579	0.0004393	21,807	-0.7936
Intervention + 81% specificity	200.10	0.84	539.9	317.2	38.76	84.92	2.35e-07	2.667e-06	20.66	84.46	179.4	196.3	191.2	3.273	9.221	605	6.829	11.67	0.0004393	26,556	-2.88
Intervention + 76% specificity	198.80	-0.49	539.9	311.5	38.76	90.63	2.35e-07	2.667e-06	20.66	90.13	179.4	196.3	191.2	3.273	9.221	607.10	6.829	13.75	0.0004393	31,306	-4.967
Intervention + 38% spirometry available	203.90	4.69	540.7	334.1	37.93	67.98	2.35e-07	2.667e-06	20.21	67.61	179.6	196.4	191.4	3.273	9.221	599.10	6.829	5.746	0.0006523	8,810	7.299
Intervention + 43% spirometry available	203.80	4.56	541.5	333.9	37.1	68.15	2.35e-07	2.667e-06	19.77	67.78	179.7	196.6	191.5	3.273	9.221	599.40	6.83	6.086	0.0008653	7,034	11.22

			Terminal node/end state occupancy (patients)																		
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Intervention + 48% spirometry available	203.70	4.42	542.4	333.8	36.27	68.33	2.35e-07	2.667e-06	19.32	67.95	179.9	196.8	191.7	3.273	9.221	599.80	6.83	6.426	0.001078	5,960	15.14
Intervention + 5% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0 (FP)	204.10	4.83	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	42.15	179.4	196.3	191.2	3.273	9.221	591	6.829	-2.295	0.0004393	Dominant	11.08
Intervention + ArtiQ costs	194.30	-4.94	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	589.30	6.829	-4.005	0.0004393	Dominant	12.79
Intervention + GoSpiro costs	194.80	-4.48	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	589.80	6.829	-3.56	0.0004393	Dominant	12.35
Intervention + NuvoAir costs	237.10	37.84	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	630.60	6.829	37.22	0.0004393	84,731	-28.44
Intervention + NuvoAir costs (removal of internet costs)	233.10	33.84	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	626.70	6.829	33.37	0.0004393	75,970	-24.59
Intervention + NuvoAir costs (removal of internet costs) + 57% sens	229.30	30.02	541.6	334.3	37.05	67.81	2.35e-07	2.667e-06	19.74	67.43	179.7	196.6	191.5	3.273	9.221	623.80	6.83	30.44	0.0008786	34,650	-12.87
Intervention + NuvoAir costs (removal of internet costs) + 67% sens	225.40	26.19	543.3	334.3	35.33	67.81	2.35e-07	2.667e-06	18.83	67.43	180	196.9	191.8	3.273	9.221	620.90	6.83	27.51	0.001318	20,877	-1.156
Intervention + NuvoAir costs (removal of internet costs) + 77% sens	221.60	22.36	545	334.3	33.61	67.81	2.35e-07	2.667e-06	17.91	67.43	180.3	197.2	192.1	3.272	9.221	617.90	6.83	24.58	0.001757	13,991	10.56
Intervention + NuvoAir costs (removal of internet costs) + 87% sens	217.80	18.54	546.7	334.3	31.89	67.81	2.35e-07	2.667e-06	16.99	67.43	180.6	197.6	192.4	3.272	9.221	615	6.831	21.65	0.002196	9,859	22.28
Intervention + NuvoAir costs (removal of internet costs) + 10% where spirometry results unavailable	235.30	36.03	539.3	334.4	39.31	67.69	2.35e-07	2.667e-06	20.95	67.32	179.3	196.2	191.2	3.273	9.222	628.50	6.829	35.17	0.0002987	117,725	-29.19
Intervention + NuvoAir costs (removal of internet costs) + more test availability (80% in 6 months)	236.90	37.67	542.2	336.8	40.79	68.32	1.776e-12	2.017e-11	21.46	67.94	178.3	195.1	189.8	3.257	9.215	637.40	6.835	44.06	0.006455	6,826	85.04
Intervention + NuvoAir costs (removal of internet costs) + more test availability (70% in 6 months)	236.90	37.67	539.9	335.4	40.62	68.04	4.533e-09	5.145e-08	21.52	67.66	178.8	195.6	190.4	3.266	9.219	633	6.831	39.65	0.002771	14,308	15.77
Intervention + NuvoAir costs (removal of internet costs) + more test	236.90	37.67	539.2	334.9	40.56	67.94	2.861e-08	3.247e-07	21.54	67.56	178.9	195.7	190.7	3.269	9.22	631.60	6.83	38.21	0.001582	24,150	-6.567

			Terminal node/end state occupancy (patients)																		
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
availability (67% in 6 months)																					
Intervention + NuvoAir costs (removal of internet costs) + more test availability (66% in 6 months)	236.90	37.67	538.9	334.8	40.54	67.91	5.094e-08	5.781e-07	21.55	67.53	179	195.8	190.7	3.27	9.22	631.10	6.83	37.72	0.001175	32,109	-14.23
Intervention + NuvoAir costs (removal of internet costs) + more test availability (65% in 6 months)	236.90	37.67	538.6	334.6	40.52	67.87	8.919e-08	1.012e-06	21.56	67.5	179	195.9	190.8	3.271	9.221	630.60	6.829	37.22	0.0007611	48,905	-22
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 3 months)	236.90	37.67	543.5	337.6	40.89	68.49	9.303e-16	1.057e-14	21.42	68.1	178.1	194.8	189.4	3.251	9.213	640.10	6.837	46.78	0.008733	5,357	127.9
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 4 months)	236.90	37.67	541.7	336.5	40.75	68.26	1.491e-11	1.694e-10	21.47	67.88	178.4	195.2	189.9	3.259	9.216	636.40	6.834	43.07	0.005627	7,655	69.47
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 5 months)	236.90	37.67	539.9	335.4	40.62	68.03	4.932e-09	5.598e-08	21.52	67.66	178.8	195.6	190.4	3.266	9.219	632.90	6.831	39.58	0.00272	14,553	14.81
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 168.625 days)	236.90	37.67	539	334.8	40.55	67.91	4.728e-08	5.366e-07	21.55	67.54	179	195.8	190.7	3.27	9.22	631.10	6.83	37.79	0.001229	30,757	-13.22
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 175 days)	236.90	37.67	538.5	334.5	40.51	67.86	1.088e-07	1.235e-06	21.56	67.49	179.1	195.9	190.8	3.271	9.221	630.40	6.829	37.04	0.0006096	60,764	-24.85
Comparator + younger (16 years)	199.30	NA	538.2	334.4	40.49	67.82	2.364e-07	2.683e-06	21.71	67.78	180.3	197.2	192.2	3.294	3.485	594.40	6.975	NA	NA	NA	NA
Intervention + younger (16 years)	204.10	4.83	540	334.4	38.77	67.82	2.364e-07	2.683e-06	20.79	67.78	180.6	197.5	192.4	3.294	3.485	599.80	6.975	5.409	0.0004485	12,060	3.561
Comparator + older (40 years)	199.30	NA	537.9	334.1	40.47	67.78	2.321e-07	2.634e-06	21.29	66.72	176.8	193.4	188.5	3.23	21.19	591.10	6.632	NA	NA	NA	NA
Intervention + older (40 years)	204.10	4.83	539.6	334.1	38.75	67.78	2.321e-07	2.634e-06	20.38	66.72	177.1	193.7	188.7	3.23	21.18	596.50	6.633	5.401	0.000427	12,648	3.14

			Terminal node/end state occupancy (patients)																		
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Comparator + 2 year time horizon	199.30	NA	527.6	327.7	39.69	66.48	11.87	7.72	35.8	66.34	152	185.2	206.1	3.29	1.204	261.70	1.567	NA	NA	NA	NA
Intervention + 2 year time horizon	204.10	4.83	529.3	327.7	38.01	66.48	11.87	7.72	34.28	66.34	152.4	185.7	206.7	3.289	1.204	266.40	1.567	4.728	8.861e-05	53,352	-2.955
Comparator + 20 year time horizon	199.30	NA	538.1	334.3	40.48	67.81	5.456e-17	8.322e-15	10.94	66.18	179.9	196.6	186.6	3.195	30.35	896.30	11.5	NA	NA	NA	NA
Intervention + 20 year time horizon	204.10	4.83	539.9	334.3	38.76	67.81	5.456e-17	8.322e-15	10.47	66.18	180.1	196.7	186.7	3.194	30.35	902	11.5	5.709	0.0006245	9,142	6.781
Comparator + 8 % prevalence	218.20	NA	74.19	762.6	5.581	154.7	3.435e-07	3.849e-06	2.97	153.5	24.65	26.97	26.28	0.4504	8.187	358.20	7.516	NA	NA	NA	NA
Intervention + 8% prevalence	226.40	8.13	74.42	762.6	5.344	154.7	3.435e-07	3.849e-06	2.844	153.5	24.69	27.01	26.32	0.4504	8.187	366.30	7.516	8.069	6.037e-05	133,656	-6.861
Comparator + 20 % prevalence	213.80	NA	184.7	660.6	13.9	134	3.142e-07	3.531e-06	7.399	133.1	61.41	67.18	65.46	1.122	8.433	414.10	7.353	NA	NA	NA	NA
Intervention + 20% prevalence	221.10	7.35	185.3	660.6	13.31	134	3.142e-07	3.531e-06	7.084	133.1	61.51	67.29	65.56	1.122	8.433	421.50	7.353	7.434	0.0001504	49,415	-4.425
Comparator + 36 % prevalence	207.80	NA	330.8	525.7	24.89	106.6	2.789e-07	3.147e-06	13.25	106	110	120.4	117.3	2.01	8.759	488.10	7.136	NA	NA	NA	NA
Intervention + 36% prevalence	214.10	6.32	331.9	525.7	23.83	106.6	2.789e-07	3.147e-06	12.69	106	110.2	120.6	117.5	2.01	8.759	494.70	7.137	6.596	0.0002697	24,460	-1.203
Comparator + 80 % prevalence	191.40	NA	724.8	162	54.52	32.86	2.01e-07	2.293e-06	29.07	32.7	241.5	264.1	257.4	4.412	9.639	688.40	6.551	NA	NA	NA	NA
Intervention + 80% prevalence	194.90	3.46	727.1	162	52.21	32.86	2.01e-07	2.293e-06	27.84	32.7	241.9	264.6	257.8	4.411	9.639	692.70	6.552	4.336	0.0005924	7,319	7.512
Comparator + increased sensitivity of Alt testing (10%)	191.50	NA	541.6	334.3	36.99	67.81	2.35e-07	2.667e-06	19.71	67.43	179.7	196.6	191.6	3.273	9.221	587.40	6.83	NA	NA	NA	NA
Intervention + increased sensitivity of Alt testing (10%)	196.30	4.83	543.3	334.3	35.28	67.81	2.35e-07	2.667e-06	18.8	67.43	180	196.9	191.8	3.273	9.221	592.80	6.83	5.406	0.0004393	12,307	3.379
Comparator + 0% undiagnosed treated	199.30	NA	538.1	334.2	40.48	67.8	2.864e-06	0	21.57	67.43	179.1	196	191	3.273	9.222	589.20	6.826	NA	NA	NA	NA
Intervention + 0% undiagnosed treated	204.10	4.83	539.8	334.2	38.76	67.8	2.864e-06	0	20.65	67.43	179.4	196.3	191.3	3.273	9.222	594.60	6.826	5.406	0.0004393	12,307	3.379
Comparator + 50% undiagnosed treated	199.30	NA	538.2	334.3	40.49	67.81	1.929e-08	2.893e-06	21.57	67.44	179.1	196	190.9	3.273	9.222	596.60	6.831	NA	NA	NA	NA
Intervention + 50% undiagnosed treated	204.10	4.83	539.9	334.3	38.77	67.81	1.929e-08	2.893e-06	20.66	67.44	179.4	196.3	191.2	3.273	9.221	602	6.831	5.407	0.0004393	12,307	3.38
Comparator + equal split across levels of asthma	199.30	NA	538.1	334.3	40.48	67.81	2.35e-07	2.667e-06	21.57	67.43	203.2	202.4	160.4	3.266	9.222	593.10	6.85	NA	NA	NA	NA

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
of control (start, and after exac)																					
Intervention + equal split across levels of asthma of control (start, and after exac)	204.10	4.83	539.9	334.3	38.77	67.81	2.35e-07	2.667e-06	20.66	67.43	203.6	202.8	160.6	3.266	9.221	598.50	6.851	5.406	0.0004884	11,070	4.361
Comparator + 5% go from controlled/pcontrol to uncontrolled	199.30	NA	538.1	334.3	40.48	67.81	2.35e-07	2.667e-06	21.57	67.44	154.2	170.6	241.3	3.283	9.222	593.50	6.811	NA	NA	NA	NA
Intervention + 5% go from controlled/pcontrol to uncontrolled	204.10	4.83	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	154.4	170.8	241.7	3.283	9.221	599	6.811	5.407	0.0003957	13,664	2.508
Comparator + utility decrement 0.01 (FP)	199.30	NA	538.1	334.3	40.48	67.81	2.35e-07	2.667e-06	21.57	67.44	179.1	196	191	3.273	9.222	593.30	6.823	NA	NA	NA	NA
Intervention + 2.5% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	204.10	4.83	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	53.31	179.4	196.3	191.2	3.273	9.221	594.60	6.824	1.268	0.0009912	1,279	18.56
Intervention + 5% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	204.10	4.83	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	42.15	179.4	196.3	191.2	3.273	9.221	591	6.825	-2.295	0.001466	Dominant	31.62
Comparator + time exac increased to 6 weeks	199.30	NA	535.1	332.4	40.26	67.42	2.119e-07	2.413e-06	17.99	67.08	180.5	197.5	192.5	4.537	9.226	601.50	6.825	NA	NA	NA	NA
Intervention + time exac increased to 6 weeks	204.10	4.83	536.8	332.4	38.55	67.42	2.119e-07	2.413e-06	17.22	67.08	180.8	197.7	192.7	4.537	9.226	606.80	6.826	5.322	0.000407	13,076	2.818
Comparator + 100% increase in monitoring costs	199.30	NA	538.1	334.3	40.48	67.81	2.35e-07	2.667e-06	21.57	67.44	179.1	196	191	3.273	9.222	742.80	6.829	NA	NA	NA	NA
Intervention + 100% increase in monitoring costs	204.10	4.83	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	748.50	6.829	5.711	0.0004393	13,000	3.075
Comparator + 100% increase in costs of exacerbation	199.30	NA	538.1	334.3	40.48	67.81	2.35e-07	2.667e-06	21.57	67.44	179.1	196	191	3.273	9.222	619.20	6.829	NA	NA	NA	NA
Intervention + 100% increase in costs of exacerbation	204.10	4.83	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	624.60	6.829	5.401	0.0004393	12,294	3.385
Comparator + lower cost of further testing (£24.32)	52.00	NA	538.1	334.3	40.48	67.81	2.35e-07	2.667e-06	21.57	67.44	179.1	196	191	3.273	9.222	451.40	6.829	NA	NA	NA	NA
Intervention + lower cost of further testing (£24.32)	60.17	8.17	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	460	6.829	8.639	0.0004393	19,665	0.1473

			Terminal node/end state occupancy (patients)																		
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Comparator + SPIRO AID sens/spec [AiC]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	NA	NA	NA	NA
Intervention + SPIRO AID sens/spec [AiC]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Comparator + doubled baseline exac rate (from controlled state)	199.30	NA	528	328	39.72	66.53	1.507e-07	1.736e-06	21.1	66.3	168.3	197.3	204.4	6.471	9.24	616.70	6.813	NA	NA	NA	NA
Intervention + doubled baseline exac rate (from controlled state)	204.10	4.83	529.7	328	38.04	66.53	1.507e-07	1.736e-06	20.21	66.3	168.6	197.6	204.7	6.475	9.24	622	6.813	5.352	0.0004163	12,856	2.974
Comparator + partial 5% increase in exac, uncontrolled 10% increased in exac	199.30	NA	537.7	334	40.45	67.75	2.301e-07	2.65e-06	20.92	67.39	180.9	197.4	188.6	3.357	9.223	594.30	6.829	NA	NA	NA	NA
Intervention + partial 5% increase in exac, uncontrolled 10% increased in exac	204.10	4.83	539.4	334	38.73	67.75	2.301e-07	2.65e-06	20.04	67.39	181.2	197.7	188.9	3.357	9.222	599.70	6.83	5.391	0.0004362	12,360	3.333
Comparator with GP for interpretation	211.20	NA	538.1	334.3	40.48	67.81	2.35e-07	2.667e-06	21.57	67.44	179.1	196	191	3.273	9.222	604.80	6.829	NA	NA	NA	NA
Intervention (LungHealth) with GP for consultation/interpretation	228.00	16.76	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	621.80	6.829	16.91	0.0004393	38,495	-8.125
Intervention (ArtiQ.Spiro) with GP for interpretation	207.70	-3.49	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	602.20	6.829	-2.602	0.0004393	-5,924	11.39
Intervention (GoSpiro) with GP for interpretation	208.20	-3.02	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	602.70	6.829	-2.157	0.0004393	-4,910	10.94
Intervention (NuvoAir) – interpretation included in cost	237.10	25.9	539.9	334.3	38.76	67.81	2.35e-07	2.667e-06	20.66	67.43	179.4	196.3	191.2	3.273	9.221	630.60	6.829	25.72	0.0004393	58,543	-16.93

Abbreviations: ICER, Incremental cost-effectiveness ratio; NMB, Net monetary benefit; QALY, Quality adjusted life year.

Asthma (children)

			Terminal node/end state occupancy (patients)																		
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Comparator	141.40	NA	526.2	257.1	53.66	145.9	2.479e-07	2.809e-06	30.74	146.1	179.3	194.6	187.6	2.962	1.257	661.30	7.375	NA	NA	NA	NA
Intervention (LungHealth costs) + 78% sensitivity	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	668.20	7.377	6.866	0.001188	5,781	16.89

			Terminal node/end state occupancy (patients)																		
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Intervention + 70% objective testing	150.00	8.65	527.8	257.8	53.82	146.4	4.786e-09	5.424e-08	30.67	146.5	179	194.3	187.1	2.956	1.256	673.60	7.377	12.29	0.002101	5,849	29.73
Intervention + 80% objective testing	150.00	8.65	529.8	258.8	54.02	146.9	1.879e-12	2.131e-11	30.59	147.1	178.6	193.9	186.5	2.948	1.255	678.80	7.38	17.5	0.004948	3,537	81.46
Intervention + 90% objective testing	150.00	8.65	531.5	259.6	54.2	147.4	2.754e-18	3.126e-17	30.52	147.6	178.3	193.5	186	2.942	1.254	683.80	7.383	22.52	0.00775	2,905	132.5
Intervention + 100% objective testing	150.00	8.65	533.6	260.6	54.41	148	9.382e-38	1.068e-36	30.44	148.1	177.8	193	185.4	2.934	1.252	690	7.387	28.72	0.0113	2,541	197.3
Intervention + 70% tested	146.20	4.82	531.9	257.8	49.79	146.4	4.786e-09	5.424e-08	28.38	146.5	179.8	195.1	187.9	2.955	1.256	672.10	7.379	10.8	0.003303	3,271	55.25
Intervention + 73% sensitivity	148.10	6.73	528.3	257.1	51.65	145.9	2.479e-07	2.809e-06	29.59	146.1	179.7	195	188	2.962	1.257	668.90	7.376	7.61	0.0005938	12,815	4.267
Intervention + 83% sensitivity	144.30	2.91	532.3	257.1	47.63	145.9	2.479e-07	2.809e-06	27.29	146.1	180.5	195.8	188.7	2.961	1.257	667.40	7.377	6.122	0.001782	3,436	29.51
Intervention + 88% sensitivity	142.40	0.99	534.3	257.1	45.62	145.9	2.479e-07	2.809e-06	26.14	146.1	180.8	196.3	189.1	2.961	1.257	666.70	7.378	5.377	0.002375	2,264	42.13
Intervention + 93% sensitivity	140.50	-0.92	536.3	257.1	43.61	145.9	2.479e-07	2.809e-06	24.98	146.1	181.2	196.7	189.4	2.961	1.257	665.90	7.378	4.633	0.002969	1,560	54.75
Intervention + 98% sensitivity	138.60	-2.83	538.3	257.1	41.6	145.9	2.479e-07	2.809e-06	23.83	146.1	181.6	197.1	189.8	2.961	1.257	665.20	7.379	3.889	0.003563	1,091	67.37
Intervention + 66% specificity	143.60	2.16	530.3	245.5	49.64	157.5	2.479e-07	2.809e-06	28.44	157.7	180.1	195.4	188.3	2.961	1.257	673.80	7.377	12.55	0.001188	10,563	11.21
Intervention + 71% specificity	144.90	3.49	530.3	251.3	49.64	151.7	2.479e-07	2.809e-06	28.44	151.9	180.1	195.4	188.3	2.961	1.257	671	7.377	9.706	0.001188	8,172	14.05
Intervention + 81% specificity	147.50	6.15	530.3	262.8	49.64	140.1	2.479e-07	2.809e-06	28.44	140.3	180.1	195.4	188.3	2.961	1.257	665.30	7.377	4.026	0.001188	3,390	19.73
Intervention + 86% specificity	148.90	7.48	530.3	268.6	49.64	134.4	2.479e-07	2.809e-06	28.44	134.5	180.1	195.4	188.3	2.961	1.257	662.50	7.377	1.186	0.001188	998.7	22.57
Intervention + 38% spirometry available	146.50	5.12	532	257.8	47.93	145.2	2.479e-07	2.809e-06	27.46	145.4	180.4	195.8	188.6	2.961	1.257	668.90	7.377	7.591	0.001692	4,488	26.24
Intervention + 43% spirometry available	146.80	5.42	533.7	258.5	46.23	144.5	2.479e-07	2.809e-06	26.48	144.7	180.7	196.1	189	2.961	1.257	669.60	7.378	8.316	0.002195	3,788	35.59
Intervention + 48% spirometry available	147.10	5.72	535.4	259.2	44.52	143.8	2.479e-07	2.809e-06	25.51	144	181.1	196.5	189.3	2.961	1.257	670.30	7.378	9.042	0.002699	3,350	44.94
Intervention + ArtiQ costs	136.40	-4.94	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	658.70	7.377	-2.566	0.001188	Dominant	26.32
Intervention + GoSpiro costs	136.90	-4.48	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	659.20	7.377	-2.12	0.001188	Dominant	25.87
Intervention + NuvoAir costs	179.20	37.83	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	700	7.377	38.75	0.001188	32,627	-15

			Terminal node/end state occupancy (patients)																		
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Intervention + NuvoAir costs (removal of internet costs)	175.20	33.84	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	696.20	7.377	34.89	0.001188	29,380	-11.14
Intervention + NuvoAir costs (removal of internet costs) + 10% where spirometry results unavailable	177.10	35.73	529.1	256.6	50.76	146.4	2.479e-07	2.809e-06	29.08	146.6	179.9	195.2	188.1	2.962	1.257	697.70	7.376	36.44	0.0008551	42,611	-19.33
Intervention + NuvoAir costs (removal of internet costs) + more test availability (80% in 6 months)	179.10	37.66	529.8	258.8	54.02	146.9	1.879e-12	2.131e-11	30.59	147.1	178.6	193.9	186.5	2.948	1.255	707.20	7.38	45.9	0.004948	9,276	53.07
Intervention + NuvoAir costs (removal of internet costs) + more test availability (70% in 6 months)	179.10	37.66	527.8	257.8	53.82	146.4	4.786e-09	5.424e-08	30.67	146.5	179	194.3	187.1	2.956	1.256	701.80	7.377	40.48	0.002101	19,269	1.537
Intervention + NuvoAir costs (removal of internet costs) + more test availability (67% in 6 months)	179.10	37.66	527.2	257.5	53.75	146.2	3.019e-08	3.421e-07	30.7	146.4	179.1	194.4	187.3	2.958	1.256	700	7.377	38.73	0.001195	32,402	-14.82
Intervention + NuvoAir costs (removal of internet costs) + more test availability (66% in 6 months)	179.10	37.66	526.9	257.4	53.73	146.1	5.375e-08	6.091e-07	30.71	146.3	179.2	194.5	187.4	2.959	1.256	699.40	7.376	38.12	0.0008861	43,021	-20.4
Intervention + NuvoAir costs (removal of internet costs) + more test availability (65% in 6 months)	179.10	37.66	526.7	257.3	53.7	146	9.41e-08	1.066e-06	30.72	146.2	179.2	194.5	187.5	2.96	1.257	698.80	7.376	37.51	0.0005733	65,427	-26.04
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 3 months)	179.10	37.66	530.9	259.3	54.13	147.2	9.861e-16	1.119e-14	30.55	147.4	178.4	193.6	186.2	2.944	1.254	710.50	7.382	49.23	0.006735	7,310	85.47
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 4 months)	179.10	37.66	529.4	258.6	53.97	146.8	1.577e-11	1.788e-10	30.61	147	178.7	194	186.7	2.95	1.255	706	7.38	44.68	0.004303	10,384	41.38
Intervention + NuvoAir costs (removal of internet costs) + more test	179.10	37.66	527.8	257.8	53.81	146.4	5.207e-09	5.902e-08	30.68	146.5	179	194.3	187.1	2.956	1.256	701.70	7.377	40.41	0.002062	19,597	0.8319

			Terminal node/end state occupancy (patients)																		
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
availability (63.2% in 5 months)																					
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 168.625 days)	179.10	37.66	527	257.4	53.73	146.1	4.989e-08	5.653e-07	30.71	146.3	179.2	194.5	187.4	2.959	1.256	699.50	7.376	38.2	0.0009268	41,218	-19.67
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 175 days)	179.10	37.66	526.6	257.2	53.69	146	1.148e-07	1.301e-06	30.73	146.2	179.3	194.6	187.5	2.96	1.257	698.60	7.376	37.29	0.0004589	81,248	-28.11
Intervention + NuvoAir costs (removal of internet costs) + 73% sens	177.10	35.75	528.3	257.1	51.65	145.9	2.479e-07	2.809e-06	29.59	146.1	179.7	195	188	2.962	1.257	696.90	7.376	35.64	0.0005938	60,013	-23.76
Intervention + NuvoAir costs (removal of internet costs) + 83% sens	173.30	31.92	532.3	257.1	47.63	145.9	2.479e-07	2.809e-06	27.29	146.1	180.5	195.8	188.7	2.961	1.257	695.40	7.377	34.15	0.001782	19,169	1.481
Intervention + 5% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0 (FP)	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	91.32	180.1	195.4	188.3	2.961	1.257	648.10	7.377	-13.17	0.001188	Dominant	36.92
Comparator + older (9 years)	141.40	NA	526.3	257.1	53.66	145.9	2.477e-07	2.807e-06	30.71	146	179.2	194.5	187.4	2.959	2.02	661.20	7.373	NA	NA	NA	NA
Intervention + older (9 years)	146.20	4.82	530.3	257.1	49.64	145.9	2.477e-07	2.807e-06	28.41	146	179.9	195.3	188.2	2.959	2.019	668.10	7.375	6.865	0.001187	5,782	16.88
Comparator + older (12 years)	141.40	NA	526.2	257.1	53.66	145.9	2.474e-07	2.803e-06	30.66	145.9	178.9	194.2	187.1	2.955	3.279	660.90	7.365	NA	NA	NA	NA
Intervention + older (12 years)	146.20	4.82	530.3	257.1	49.64	145.9	2.474e-07	2.803e-06	28.37	145.9	179.6	195	187.9	2.954	3.278	667.80	7.367	6.864	0.001186	5,787	16.86
Comparator + 2 year time horizon	141.40	NA	515.8	252	52.59	143	11.99	7.796	47.97	142.8	149	180.8	201.5	2.955	0.1826	228.40	1.675	NA	NA	NA	NA
Intervention + 2 year time horizon	146.20	4.82	519.8	252	48.66	143	11.99	7.796	44.38	142.8	150	182	202.9	2.955	0.1826	233.50	1.675	5.04	0.0002315	21,768	-0.4094
Comparator + 5 year time horizon	141.40	NA	526.2	257	53.65	145.9	0.01575	0.03945	41.28	146.2	170.7	186.5	194.4	2.968	0.4648	404.90	3.997	NA	NA	NA	NA
Intervention + 5 year time horizon	146.20	4.82	530.2	257	49.63	145.9	0.01575	0.03945	38.19	146.2	171.7	187.5	195.5	2.968	0.4648	410.80	3.997	5.931	0.0006618	8,962	7.305
Comparator + 8% prevalence	170.70	NA	72.42	585.5	7.384	332.4	3.482e-07	3.901e-06	4.226	332.2	24.64	26.74	25.78	0.4069	0.9151	465.80	7.78	NA	NA	NA	NA
Intervention + 8% prevalence	178.80	8.13	72.98	585.5	6.831	332.4	3.482e-07	3.901e-06	3.909	332.2	24.74	26.85	25.88	0.4069	0.9151	474.10	7.781	8.272	0.000163	50,746	-5.012

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Comparator + 20% prevalence	163.80	NA	180.4	507.3	18.4	288	3.215e-07	3.611e-06	10.53	287.9	61.4	66.65	64.24	1.014	0.9963	512.20	7.684	NA	NA	NA	NA
Intervention + 20% prevalence	171.20	7.35	181.8	507.3	17.02	288	3.215e-07	3.611e-06	9.741	287.9	61.66	66.92	64.49	1.014	0.9963	520.20	7.685	7.936	0.0004063	19,531	0.1904
Comparator + 36% prevalence	154.60	NA	323.3	403.9	32.96	229.3	2.89e-07	3.258e-06	18.87	229.4	110.1	119.5	115.2	1.818	1.104	573.70	7.557	NA	NA	NA	NA
Intervention + 36% prevalence	160.90	6.31	325.7	403.9	30.49	229.3	2.89e-07	3.258e-06	17.46	229.4	110.5	120	115.6	1.818	1.104	581.20	7.558	7.494	0.0007286	10,285	7.079
Comparator + 80% prevalence	129.30	NA	709.3	124.6	72.32	70.76	2.155e-07	2.453e-06	41.45	70.89	241.9	262.5	253	3.995	1.395	740.50	7.211	NA	NA	NA	NA
Intervention + 80% prevalence	132.80	3.46	714.7	124.6	66.9	70.76	2.155e-07	2.453e-06	38.35	70.89	242.9	263.6	254	3.994	1.395	746.80	7.213	6.301	0.001603	3,932	25.75
Comparator + increased sensitivity of Alt testing (10%)	133.60	NA	534.4	257.1	45.5	145.9	2.479e-07	2.809e-06	26.07	146.1	180.9	196.3	189.1	2.961	1.257	658.30	7.378	NA	NA	NA	NA
Intervention + increased sensitivity of Alt testing (10%)	138.40	4.82	538.4	257.1	41.48	145.9	2.479e-07	2.809e-06	23.76	146.1	181.6	197.1	189.8	2.961	1.257	665.10	7.379	6.866	0.001188	5,781	16.89
Comparator + 0% undiagnosed treated	141.40	NA	526.2	257	53.65	145.9	3.021e-06	0	30.74	146.1	179.3	194.7	187.6	2.962	1.257	656.30	7.372	NA	NA	NA	NA
Intervention + 0% undiagnosed treated	146.20	4.82	530.2	257	49.63	145.9	3.021e-06	0	28.44	146.1	180.1	195.5	188.4	2.962	1.257	663.20	7.373	6.865	0.001188	5,781	16.89
Comparator + 50% undiagnosed treated	141.40	NA	526.3	257.1	53.66	145.9	2.034e-08	3.046e-06	30.74	146.1	179.3	194.6	187.6	2.962	1.257	665.30	7.378	NA	NA	NA	NA
Intervention + 50% undiagnosed treated	146.20	4.82	530.3	257.1	49.64	145.9	2.034e-08	3.046e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	672.20	7.379	6.866	0.001188	5,781	16.89
Comparator + equal split across levels of asthma of control (start, and after exac)	141.40	NA	526.2	257.1	53.66	145.9	2.479e-07	2.809e-06	30.74	146.1	202.3	201.5	157.7	2.955	1.257	661.10	7.399	NA	NA	NA	NA
Intervention + equal split across levels of asthma of control (start, and after exac)	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	203.1	202.4	158.4	2.955	1.257	668	7.4	6.865	0.001318	5,208	19.5
Comparator + 5% go from controlled/pcontrol to uncontrolled	141.40	NA	526.2	257.1	53.66	145.9	2.479e-07	2.809e-06	30.74	146.1	153.1	168	240.5	2.971	1.257	661.50	7.355	NA	NA	NA	NA
Intervention + 5% go from controlled/pcontrol to uncontrolled	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	153.7	168.7	241.5	2.971	1.257	668.40	7.356	6.867	0.001065	6,447	14.44
Comparator + 10% go from controlled/pcontrol to uncontrolled	141.40	NA	526.2	257.1	53.66	145.9	2.479e-07	2.809e-06	30.74	146.1	130.2	144.7	286.6	2.98	1.257	661.70	7.336	NA	NA	NA	NA

			Terminal node/end state occupancy (patients)																		
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Intervention + 10% go from controlled/pcontrol to uncontrolled	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	130.8	145.3	287.8	2.979	1.257	668.50	7.337	6.868	0.0009504	7,226	12.14
Comparator + time exac increased to 6 weeks	141.40	NA	523.6	255.8	53.38	145.2	2.259e-07	2.568e-06	26.11	145.4	181	196.5	189.5	4.105	1.258	669.60	7.374	NA	NA	NA	NA
Intervention + time exac increased to 6 weeks	146.20	4.82	527.6	255.8	49.39	145.2	2.259e-07	2.568e-06	24.16	145.4	181.7	197.2	190.1	4.104	1.258	676.30	7.375	6.688	0.001108	6,037	15.47
Comparator + 100% in monitoring costs	141.40	NA	526.2	257.1	53.66	145.9	2.479e-07	2.809e-06	30.74	146.1	179.3	194.6	187.6	2.962	1.257	826.90	7.375	NA	NA	NA	NA
Intervention + 100% in monitoring costs	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	834.50	7.377	7.6	0.001188	6,399	16.15
Comparator + 100% increase in costs of exacerbation	141.40	NA	526.2	257.1	53.66	145.9	2.479e-07	2.809e-06	30.74	146.1	179.3	194.6	187.6	2.962	1.257	684.70	7.375	NA	NA	NA	NA
Intervention + 100% increase in costs of exacerbation	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	691.50	7.377	6.853	0.001188	5,770	16.9
Comparator + lower cost of further testing (£24.32)	44.84	NA	526.2	257.1	53.66	145.9	2.479e-07	2.809e-06	30.74	146.1	179.3	194.6	187.6	2.962	1.257	568	7.375	NA	NA	NA	NA
Intervention + lower cost of further testing (£24.32)	53.01	8.17	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	578.10	7.377	10.11	0.001188	8,508	13.65
Comparator + utility decrement 0.01 (FP)	141.40	NA	526.2	257.1	53.66	145.9	2.479e-07	2.809e-06	30.74	146.1	179.3	194.6	187.6	2.962	1.257	661.30	7.364	NA	NA	NA	NA
Intervention + 2.5% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	115.5	180.1	195.4	188.3	2.961	1.257	657.40	7.366	-3.903	0.00238	Dominant	51.49
Intervention + 5% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	91.32	180.1	195.4	188.3	2.961	1.257	648.10	7.367	-13.17	0.003405	Dominant	81.28
Intervention +10% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	57.11	180.1	195.4	188.3	2.961	1.257	633.20	7.369	-28.11	0.005059	Dominant	129.3
Intervention + 25% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	14.04	180.1	195.4	188.3	2.961	1.257	606.50	7.372	-54.83	0.008016	Dominant	215.2
Intervention + 50% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	1.378	180.1	195.4	188.3	2.961	1.257	588.20	7.374	-73.12	0.01004	Dominant	273.9

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Intervention + 75% from 'no disease, treated' to 'no disease' + utility decrement 0.01 (FP)	146.20	4.82	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	0.1393	180.1	195.4	188.3	2.961	1.257	580.60	7.375	-80.69	0.01088	Dominant	298.3
Comparator + doubled baseline exac rate (from controlled state)	150.00	NA	517.3	252.7	52.75	143.5	1.665e-07	1.912e-06	17.17	143.9	172.6	199.9	205.7	5.957	1.262	698.30	7.366	NA	NA	NA	NA
Intervention + doubled baseline exac rate (from controlled state)	146.20	-3.83	521.3	252.7	48.8	143.5	1.665e-07	1.912e-06	15.89	143.9	173	200.3	206.1	5.956	1.262	696.30	7.367	-1.923	0.0009075	Dominant	20.07
Comparator + partial 5% increase in exac, uncontrolled 10% increased in exac	141.40	NA	525.9	256.9	53.62	145.8	2.432e-07	2.793e-06	29.91	146	181.1	196.1	185.5	3.039	1.257	662.30	7.376	NA	NA	NA	NA
Intervention + partial 5% increase in exac, uncontrolled 10% increased in exac	146.20	4.82	529.9	256.9	49.6	145.8	2.432e-07	2.793e-06	27.67	146	181.8	196.9	186.2	3.038	1.257	669.20	7.378	6.833	0.00118	5,789	16.77
Comparator with GP for interpretation	153.30	NA	526.2	257.1	53.66	145.9	2.479e-07	2.809e-06	30.74	146.1	179.3	194.6	187.6	2.962	1.257	672.80	7.375	NA	NA	NA	NA
Intervention (LungHealth) with GP for consultation/interpretation	170.10	16.76	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	691.20	7.377	18.4	0.001188	15,488	5.358
Intervention (ArtiQ.Spiro) with GP for interpretation	149.80	-3.48	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	671.70	7.377	-1.16	0.001188	-976.9	24.91
Intervention (GoSpiro) with GP for interpretation	150.30	-3.02	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	672.10	7.377	-0.714	0.001188	-601.2	24.47
Intervention (NuvoAir) – interpretation included in cost	179.20	25.9	530.3	257.1	49.64	145.9	2.479e-07	2.809e-06	28.44	146.1	180.1	195.4	188.3	2.961	1.257	700	7.377	27.22	0.001188	22,920	-3.468

Abbreviations: ICER, Incremental cost-effectiveness ratio; NMB, Net monetary benefit; QALY, Quality adjusted life year.

COPD

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Comparator	187.70	NA	527.3	320.7	31.7	67.75	9.851e-08	1.455e-06	4.944	65.24	130.5	373.9	49.17	6.632	60.74	787.40	6.076	NA	NA	NA	NA

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Intervention (LungHealth costs) + 47% sensitivity	202.30	14.61	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	802.30	6.079	14.92	0.002498	5,974	35.03
Intervention + 70% objective testing	213.90	26.21	532.1	323.6	31.98	68.36	1.868e-09	2.772e-08	4.906	65.82	129.8	371.9	48.9	6.597	60.47	813.80	6.086	26.38	0.009178	2,874	157.2
Intervention + 80% objective testing	213.90	26.21	538.2	327.3	32.35	69.14	7.081e-13	1.061e-11	4.861	66.54	129	369.4	48.57	6.552	60.12	816.40	6.098	28.96	0.02142	1,352	399.4
Intervention + 90% objective testing	213.90	26.21	543.7	330.7	32.68	69.86	9.806e-19	1.493e-17	4.823	67.22	128.2	367.1	48.27	6.511	59.78	818.80	6.11	31.41	0.03331	942.9	634.8
Intervention + 100% objective testing	213.90	26.21	550.4	334.8	33.09	70.72	2.824e-38	4.504e-37	4.781	68.02	127.2	364.3	47.9	6.461	59.35	821.80	6.125	34.39	0.04833	711.6	932.2
Intervention + 42% sensitivity	208.10	20.41	529.8	320.7	29.18	67.75	9.851e-08	1.455e-06	4.552	65.24	130.6	374.2	49.2	6.631	60.66	807.10	6.078	19.67	0.001249	15,751	5.306
Intervention + 57% sensitivity	190.70	3.01	537.4	320.7	21.63	67.75	9.851e-08	1.455e-06	3.375	65.24	131	375.2	49.3	6.629	60.43	792.80	6.081	5.423	0.004995	1,086	94.49
Intervention + 67% sensitivity	179.10	-8.58	542.4	320.7	16.6	67.75	9.851e-08	1.455e-06	2.59	65.24	131.2	375.8	49.36	6.628	60.28	783.30	6.084	-4.076	0.007493	Dominant	153.9
Intervention + 77% sensitivity	167.50	-20.18	547.4	320.7	11.57	67.75	9.851e-08	1.455e-06	1.805	65.24	131.5	376.5	49.43	6.626	60.13	773.80	6.086	-13.57	0.009991	Dominant	213.4
Intervention + 87% sensitivity	155.90	-31.78	552.5	320.7	6.541	67.75	9.851e-08	1.455e-06	1.02	65.24	131.7	377.1	49.5	6.625	59.97	764.30	6.089	-23.07	0.01249	Dominant	272.8
Intervention + 94% specificity	200.70	13	532.4	314	26.67	74.43	9.851e-08	1.455e-06	4.159	71.68	130.8	374.6	49.23	6.631	60.58	804.10	6.079	16.67	0.002498	6,673	33.29
Intervention + 91% specificity	198.20	10.58	532.4	304	26.67	84.45	9.851e-08	1.455e-06	4.159	81.33	130.8	374.6	49.23	6.631	60.58	806.70	6.079	19.29	0.002498	7,722	30.67
Intervention + 81% specificity	190.20	2.52	532.4	270.6	26.67	117.9	9.851e-08	1.455e-06	4.159	113.5	130.8	374.6	49.23	6.631	60.58	815.40	6.079	28.02	0.002498	11,216	21.94
Intervention + 75% specificity	185.40	-2.31	532.4	250.6	26.67	137.9	9.851e-08	1.455e-06	4.159	132.8	130.8	374.6	49.23	6.631	60.58	820.70	6.079	33.25	0.002498	13,313	16.7
Intervention + ArtiQ costs	172.70	-14.98	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	774.80	6.079	-12.65	0.002498	Dominant	62.6
Intervention + GoSpiro costs	174.10	-13.58	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	776.10	6.079	-11.34	0.002498	Dominant	61.3
Intervention + NuvoAir costs	302.30	114.6	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	895.50	6.079	108.1	0.002498	43,289	-58.17
Intervention + NuvoAir costs (removal of internet costs)	290.20	102.5	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	884.30	6.079	96.85	0.002498	38,775	-46.9

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Intervention + NuvoAir costs (removal of internet costs) + 10% where spirometry results unavailable	284.40	96.72	535	322.1	24	66.41	9.851e-08	1.455e-06	3.743	63.95	130.9	374.9	49.27	6.63	60.5	878.90	6.08	91.47	0.003822	23,935	-15.04
Intervention + NuvoAir costs (removal of internet costs) + more test availability (80% in 6 months)	301.80	114.1	538.2	327.3	32.35	69.14	7.081e-13	1.061e-11	4.861	66.54	129	369.4	48.57	6.552	60.12	900.50	6.098	113.1	0.02142	5,279	315.3
Intervention + NuvoAir costs (removal of internet costs) + more test availability (70% in 6 months)	301.80	114.1	532.1	323.6	31.98	68.36	1.868e-09	2.772e-08	4.906	65.82	129.8	371.9	48.9	6.597	60.47	896.70	6.086	109.3	0.009178	11,906	74.29
Intervention + NuvoAir costs (removal of internet costs) + more test availability (67% in 6 months)	301.80	114.1	530.1	322.4	31.86	68.1	1.188e-08	1.759e-07	4.922	65.57	130.1	372.8	49.02	6.612	60.58	895.40	6.082	108	0.005239	20,619	-3.242
Intervention + NuvoAir costs (removal of internet costs) + more test availability (66% in 6 months)	301.80	114.1	529.4	322	31.82	68.01	2.121e-08	3.138e-07	4.928	65.49	130.2	373.1	49.05	6.617	60.62	895	6.08	107.6	0.003889	27,664	-29.81
Intervention + NuvoAir costs (removal of internet costs) + more test availability (65% in 6 months)	301.80	114.1	528.7	321.5	31.78	67.92	3.723e-08	5.504e-07	4.933	65.4	130.3	373.4	49.09	6.622	60.66	894.60	6.079	107.2	0.00252	42,531	-56.77
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 3 months)	301.80	114.1	541.8	329.5	32.56	69.6	3.598e-16	5.439e-15	4.836	66.98	128.4	367.9	48.38	6.525	59.9	902.80	6.105	115.4	0.02902	3,977	464.9
Intervention + NuvoAir costs (removal of internet costs) + more test	301.80	114.1	536.8	326.5	32.27	68.97	5.999e-12	8.966e-11	4.871	66.38	129.1	369.9	48.65	6.562	60.19	899.60	6.095	112.2	0.01866	6,014	261

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
availability (63.2% in 4 months)																					
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 5 months)	301.80	114.1	532	323.6	31.98	68.35	2.033e-09	3.017e-08	4.907	65.81	129.8	372	48.91	6.597	60.47	896.60	6.085	109.2	0.009009	12,123	70.96
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 168.625 days)	301.80	114.1	529.5	322	31.82	68.02	1.968e-08	2.912e-07	4.927	65.5	130.2	373	49.05	6.616	60.62	895.10	6.081	107.7	0.004067	26,468	-26.31
Intervention + NuvoAir costs (removal of internet costs) + more test availability (63.2% in 175.625 days)	301.80	114.1	528.4	321.4	31.76	67.89	4.547e-08	6.721e-07	4.936	65.37	130.4	373.5	49.11	6.624	60.68	894.40	6.078	107	0.002018	53,028	-66.64
Intervention + NuvoAir costs (removal of internet costs) + 57% sens	278.60	90.94	537.4	320.7	21.63	67.75	9.851e-08	1.455e-06	3.375	65.24	131	375.2	49.3	6.629	60.43	874.80	6.081	87.35	0.004995	17,486	12.56
Intervention + NuvoAir costs (removal of internet costs) + 67% sens	267.00	79.35	542.4	320.7	16.6	67.75	9.851e-08	1.455e-06	2.59	65.24	131.2	375.8	49.36	6.628	60.28	865.30	6.084	77.85	0.007493	10,390	72.01
Intervention + NuvoAir costs (removal of internet costs) + 77% sens	255.40	67.75	547.4	320.7	11.57	67.75	9.851e-08	1.455e-06	1.805	65.24	131.5	376.5	49.43	6.626	60.13	855.80	6.086	68.35	0.009991	6,842	131.5
Intervention + NuvoAir costs (removal of internet costs) + 87% sens	243.80	56.15	552.5	320.7	6.541	67.75	9.851e-08	1.455e-06	1.02	65.24	131.7	377.1	49.5	6.625	59.97	846.30	6.089	58.86	0.01249	4,713	190.9
Intervention + 5% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0 (FP)	202.30	14.61	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	40.74	130.8	374.6	49.23	6.631	60.58	796	6.079	8.613	0.002498	3,448	41.34
Comparator + 0% undiagnosed treated	187.70	NA	526.4	320.2	31.64	67.63	1.206e-06	0	4.934	65.13	130.6	374.2	49.21	6.637	60.97	784.90	6.068	NA	NA	NA	NA

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Intervention + 0% undiagnosed treated	202.30	14.61	531.4	320.2	26.62	67.63	1.206e-06	0	4.15	65.13	130.9	374.8	49.27	6.636	60.82	799.80	6.071	14.9	0.002494	5,974	34.98
Comparator + 50% undiagnosed treated	187.70	NA	528.1	321.2	31.74	67.85	8.05e-09	1.641e-06	4.953	65.34	130.4	373.7	49.14	6.628	60.55	789.40	6.083	NA	NA	NA	NA
Intervention + 50% undiagnosed treated	202.30	14.61	533.1	321.2	26.7	67.85	8.05e-09	1.641e-06	4.166	65.33	130.7	374.3	49.2	6.627	60.39	804.30	6.086	14.94	0.002501	5,975	35.08
Comparator + start age 40 years	187.70	NA	528.3	321.3	31.76	67.88	1.045e-07	1.504e-06	5.361	66.92	135.4	389.3	51.38	6.907	27.92	798.50	6.364	NA	NA	NA	NA
Intervention + start age (40 years)	202.30	14.61	533.4	321.3	26.72	67.88	1.045e-07	1.504e-06	4.51	66.92	135.6	389.9	51.44	6.905	27.85	813.40	6.366	14.93	0.002378	6,280	32.62
Comparator + start age 60 years	187.70	NA	525.2	319.4	31.57	67.47	8.517e-08	1.342e-06	4.044	61.29	119.3	338.5	44.07	6.001	136.6	762.90	5.65	NA	NA	NA	NA
Intervention + start age 60 years	202.30	14.61	530.2	319.4	26.56	67.47	8.517e-08	1.342e-06	3.402	61.29	119.6	339.2	44.14	6.002	136.3	777.80	5.653	14.9	0.002776	5,367	40.62
Comparator + time horizon 2 years	187.70	NA	518.4	315.3	31.16	66.6	10.03	6.791	23.26	66.43	120	375.5	63.27	7.168	10.13	304.30	1.411	NA	NA	NA	NA
Intervention + time horizon 2 years	202.30	14.61	523.4	315.3	26.21	66.6	10.03	6.791	19.57	66.43	120.8	378.1	63.65	7.154	10.1	318.20	1.411	13.87	0.0006212	22,320	-1.441
Comparator + time horizon 20 years	187.70	NA	527.3	320.7	31.7	67.75	8.399e-18	2.552e-15	0.5673	58.73	112.6	318.8	41.44	5.601	184.3	1188	9.888	NA	NA	NA	NA
Intervention + time horizon 20 years	202.30	14.61	532.4	320.7	26.67	67.75	8.399e-18	2.552e-15	0.4772	58.72	112.7	318.9	41.46	5.602	184.1	1204	9.892	15.17	0.00339	4,474	52.63
Comparator + prev 8%	220.80	NA	74.79	752.8	4.496	159	2.959e-07	3.433e-06	0.7019	152.5	18.44	52.84	6.948	0.9372	45.91	376.40	6.977	NA	NA	NA	NA
Intervention + 8% prev	245.40	24.64	75.51	752.8	3.782	159	2.959e-07	3.433e-06	0.5905	152.5	18.48	52.93	6.957	0.937	45.89	400.60	6.977	24.18	0.0003507	68,936	-17.16
Comparator + prev 20%	213.00	NA	185	647.6	11.12	136.8	2.286e-07	2.805e-06	1.736	131.3	45.65	130.8	17.2	2.32	49.51	475.90	6.759	NA	NA	NA	NA
Intervention + 20% prev	235.20	22.28	186.7	647.6	9.354	136.8	2.286e-07	2.805e-06	1.46	131.3	45.73	131	17.22	2.319	49.45	497.90	6.759	21.92	0.0008694	25,216	-4.535
Comparator + prev 36%	202.60	NA	328.3	510.8	19.73	107.9	1.619e-07	2.142e-06	3.079	103.7	81.11	232.4	30.56	4.122	54.19	605.90	6.474	NA	NA	NA	NA
Intervention + 36% prev	221.70	19.13	331.4	510.8	16.6	107.9	1.619e-07	2.142e-06	2.59	103.7	81.26	232.8	30.6	4.121	54.1	624.90	6.475	18.99	0.001548	12,271	11.96
Comparator + prev 80%	174.10	NA	702.3	153.7	42.22	32.46	6.251e-08	1.022e-06	6.584	31.32	174.1	498.8	65.59	8.847	66.51	948	5.725	NA	NA	NA	NA
Intervention + 80% prev	184.50	10.48	709.1	153.7	35.52	32.46	6.251e-08	1.022e-06	5.539	31.32	174.4	499.6	65.67	8.845	66.31	959.40	5.729	11.34	0.003341	3,395	55.47

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Comparator + 5% go from controlled/pcontrol to uncontrolled	187.70	NA	527.3	320.7	31.7	67.75	9.851e-08	1.455e-06	4.944	65.24	130.5	373.9	49.17	6.632	60.74	787.40	6.071	NA	NA	NA	NA
Intervention + 5% go from controlled/pcontrol to uncontrolled	202.30	14.61	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	802.30	6.074	14.92	0.002498	5,974	35.03
Comparator + utility decrement 0.01 (FP)	202.30	NA	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	802.30	6.074	NA	NA	NA	NA
Intervention + 2.5% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	202.30	0	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	51.55	130.8	374.6	49.23	6.631	60.58	798.90	6.074	-3.39	0.000544	Dominant	14.27
Intervention + 5% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	202.30	0	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	40.74	130.8	374.6	49.23	6.631	60.58	796	6.075	-6.309	0.001012	Dominant	26.56
Intervention +10% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	202.30	0	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	25.45	130.8	374.6	49.23	6.631	60.58	791.30	6.075	-11.02	0.001768	Dominant	46.38
Intervention + 25% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	202.30	0	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	6.233	130.8	374.6	49.23	6.631	60.58	782.90	6.077	-19.45	0.003121	Dominant	81.87
Intervention + 50% from ‘no disease, treated’ to ‘no disease’ + utility decrement 0.01 (FP)	202.30	0	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	0.6074	130.8	374.6	49.23	6.631	60.58	777.10	6.078	-25.25	0.004051	Dominant	106.3
Intervention + 75% from ‘no disease, treated’ to ‘no disease’ + utility	202.30	0	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	0.0608	130.8	374.6	49.23	6.631	60.58	774.70	6.078	-27.65	0.004437	Dominant	116.4

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
decrement 0.01 (FP)																					
Comparator + 100% increase in monitoring costs	187.70	NA	527.3	320.7	31.7	67.75	9.851e-08	1.455e-06	4.944	65.24	130.5	373.9	49.17	6.632	60.74	938.30	6.076	NA	NA	NA	NA
Intervention + 100% increase in monitoring costs	202.30	14.61	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	953.80	6.079	15.51	0.002498	6,209	34.45
Comparator + 100% increase in exacerbation costs	187.70	NA	527.3	320.7	31.7	67.75	9.851e-08	1.455e-06	4.944	65.24	130.5	373.9	49.17	6.632	60.74	978.30	6.076	NA	NA	NA	NA
Intervention + 100% increase in exacerbation costs	202.30	14.61	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	992.80	6.079	14.56	0.002498	5,828	35.4
Comparator + SPIRO AID sens/spec [AiC]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	NA	NA	NA	NA
Intervention + SPIRO AID sens/spec [AiC]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Comparator + lower cost of further testing (£24.32)	55.85	NA	527.3	320.7	31.7	67.75	9.851e-08	1.455e-06	4.944	65.24	130.5	373.9	49.17	6.632	60.74	664.60	6.076	NA	NA	NA	NA
Intervention + lower cost of further testing (£24.32)	80.63	24.78	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	689	6.079	24.39	0.002498	9,765	25.56
Comparator + 2 spirometry tests	187.70	NA	527.3	320.7	31.7	67.75	9.851e-08	1.455e-06	4.944	65.24	130.5	373.9	49.17	6.632	60.74	787.40	6.076	NA	NA	NA	NA
Intervention + NuvoAir costs (removal of internet costs) + no alternative testing	290.20	102.5	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	884.30	6.079	96.85	0.002498	38,775	-46.9
Intervention + NuvoAir costs (removal of internet costs) + no alternative testing + 10% Spirometry unavailable	284.40	96.72	535	322.1	24	66.41	9.851e-08	1.455e-06	3.743	63.95	130.9	374.9	49.27	6.63	60.5	878.90	6.08	91.47	0.003822	23,935	-15.04

			Terminal node/end state occupancy (patients)																	
Scenario	Cost Testing (£)	Incremental Cost Testing (£)	TP	TN	FN	FP	Undiagnosed awaiting testing	Undiagnosed	Disease untreated	No disease treated	Controlled	Partially controlled	Uncontrolled	Exacerbations	Deaths	Total costs (£)	Total QALYs	Incremental costs (£)	Incremental QALYs	ICER (£/QALY)	Incremental NMB (£)
Intervention + time exac increased to 6 weeks	202.30	14.61	524.7	316.1	26.28	66.77	7.433e-08	1.158e-06	2.531	64.37	131.7	377.2	49.56	9.208	60.75	857.70	6.069	14.45	0.002132	6,777	28.19
Comparator + increased HR for mortality (exac)	187.70	NA	527.3	320.7	31.69	67.75	9.84e-08	1.453e-06	4.935	65.24	130.1	372.6	48.97	6.602	62.69	786.40	6.072	NA	NA	NA	NA
Intervention + increased HR for mortality (exac)	202.30	14.61	532.3	320.7	26.66	67.75	9.84e-08	1.453e-06	4.152	65.24	130.3	373.3	49.04	6.601	62.54	801.30	6.074	14.92	0.002503	5,963	35.13
Comparator with GP for interpretation	223.80	NA	527.3	320.7	31.7	67.75	9.851e-08	1.455e-06	4.944	65.24	130.5	373.9	49.17	6.632	60.74	821.10	6.076	NA	NA	NA	NA
Intervention (LungHealth) with GP for consultation/interpretation	274.60	50.78	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	869.70	6.079	48.62	0.002498	19,467	1.331
Intervention (ArtiQ.Spiro) with GP for interpretation	213.30	-10.57	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	812.60	6.079	-8.539	0.002498	Dominant	58.49
Intervention (GoSpiro) with GP for interpretation	214.70	-9.17	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	813.90	6.079	-7.235	0.002498	Dominant	57.19
Intervention (NuvoAir) – interpretation included in cost	302.30	78.47	532.4	320.7	26.67	67.75	9.851e-08	1.455e-06	4.159	65.24	130.8	374.6	49.23	6.631	60.58	895.50	6.079	74.42	0.002498	29,796	-24.47

Abbreviations: ICER, Incremental cost-effectiveness ratio; NMB, Net monetary benefit; QALY, Quality adjusted life year.

Appendix C – Summary of additional detail on technologies

Appendix C1: Additional technical information

Device (Company) [Previous Name]	Intended Purpose	Contraindications	Disease Identification	Planned changes or updates	Training Requirements	Installation methods	Patient Data	Algorithm training and validation data
ArtiQ.Spiro [ArtiQ.PFT] (Clario)	Provide automated interpretation of PFTs to assist physicians in the diagnosis and follow-up of respiratory diseases	Patients that have had lung transplant or were diagnosed with COVID-19 in the past 2 weeks	Asthma, COPD, normal lung function, ILD, including IPF, NSIP, or unidentified (including neuromuscular disease, pulmonary vascular disease, thoracic deformity, pleural disease)	Minor updates will be made to enhance usability of the report. No impact the original performance, safety or interpretation of the data.	User manual is provided. It takes approximately 15 min to read this, install and start using the software.	No additional software installation is needed, only activation of ArtiQ in the existing Spirotrac/SpiroConnect software using the provided license key. No IT support is needed as no additional software needs to be installed. Approx. 15 minutes of installation time	Non identifiable information is sent and stored online including spirometry parameters, patient demographics such as age (not the date of birth), sex, weight, height, ethnicity, and smoking status.	[redacted] Validation: Retrospective validation study *(Sunjaya et al. 2025, ERJ Open, Table 1);* Total patients=1113 **<u>COPD (n=543)</u>** <u>Sex:</u> Male: 55.8% (n=303) Female: 44.2% (n=240) <u>Age:</u> ≤50 years: 9.9% (n=54) 51–60 years: 12.6% (n=68) 61–70 years: 37.4% (n=203) 71–80 years: 40.5% (n=220) <u>Ethnicity:</u> White: 91.5% (n=497) Other: 8.5% (n=46) **Asthma (n=107)** <u>Sex:</u> Male: 38.3% (n=41) Female: 61.7% (n=66) <u>Age:</u> ≤50 years: 64.4% (n=69) 51–60 years: 25.2% (n=27) 61–70 years: 7.5% (n=8) 80 years: 2.8% (n=3) <u>Ethnicity:</u> White: 63.6% (n=68) Other: 36.4% (n=39) **Interstitial Lung Disease (ILD) (n=249)** <u>Sex:</u> Male: 58.6% (n=146) Female: 41.4% (n=103) <u>Age:</u> ≤50 years: 10.0% (n=25) 80 years: 13.3% (n=33)

Device (Company) [Previous Name]	Intended Purpose	Contraindications	Disease Identification	Planned changes or updates	Training Requirements	Installation methods	Patient Data	Algorithm training and validation data
								(Other age bands not provided) Ethnicity: White: 56.6% (Other ethnicity data not provided) **Normal (n=30)** Sex: Male: 53.3% (n=16) Female: 46.7% (n=14) Age: <50 years: 26.7% (n=8) 51–60 years: 20.0% (n=6) 61–70 years: 23.3% (n=7) 71–80 years: 30.0% (n=9) Ethnicity: White: 80.0% (n=24) Other: 20.0% (n=6) **OBD (n=89)** Sex: Male: 39.3% (n=35) Female: 60.7% (n=54) Age: <50 years: 19.1% (n=17) 51–60 years: 11.2% (n=10) 61–70 years: 18.0% (n=16) 71–80 years: 40.4% (n=36) 80 years: 11.2% (n=10) Ethnicity: White: 75.3% (n=67) Other: 24.7% (n=22) **Unidentified (n=95)** Sex: Male: 48.5% (n=46) Female: 51.5% (n=49) Age: <50 years: 21% (n=20) 51–60 years: 12% (n=11) 61–70 years: 27% (n=26) 71–80 years: 28% (n=27) 80 years: 12% (n=11) Ethnicity: White: 81% (n=58) Other: 19% (n=13) Other characteristics were also reported: Smoking status, BMI, Mean FEV & FVC (Litres), FEV & FVC Z-Scores, and Mean FEV & FVC % predicted % included in study

Device (Company) [Previous Name]	Intended Purpose	Contraindications	Disease Identification	Planned changes or updates	Training Requirements	Installation methods	Patient Data	Algorithm training and validation data
LungHealth (LungHealth)	Provides algorithm guided consultations both face to face and remote	Spirometry contraindications	COPD, Asthma, suggestions of other respiratory diseases e.g. bronchiectasis and emphysema	None	LungHealth offers full day training and access to a test site where a new user can enter dummy patients. They are then validated in live reviews by an agreed mentor.	Installed at the local practice	Uses a series of API calls and so has a read / write back functionality to and from the patient EPR on the practice system.	**Validation:** **Chakrabarti 2025** Patients confirmed COPD (n= 4117), • Mean age = 74 (SD 10) • Sex = Male (2225 (46%)) • COPD severity GOLD 1 = 1031 GOLD 2 = 2214 GOLD 3 = 732 GOLD 4 = 140
MIR Spiro (Medical International Research, MIR)	Support Spirometry & Oximetry tests	NR	NR	NR	NR	Software installed on Desktop or Laptop	NR	NR
EasyOne Connect (NDD)	Integrated spirometry platform providing quality grading and results interpretation	NR	NR	NR	NR	Installation required by local IT team. Few hours for standard integrations Windows 7 SP1 or higher & optional SQL Server	NR	NR
GoSpiro (Monitored Therapeutics)	Conduct basic lung function and spirometry testing	Haemoptysis of unknown origin, Presence of Pneumothorax, unstable cardiovascular status, Recent (within 1 month) myocardial infarction, Uncontrolled hypertension, Pulmonary embolism, Haemorrhagic cerebrovascular event Unstable angina, Recent thoracic, abdominal or eye surgery, Nausea, vomiting or abdominal pain, Thoracic or abdominal aneurysms, history of syncope associated with forced exhalation, Active tuberculosis or Hepatitis B	Can be used to suggest obstructive or restrictive diseases, or a combination of both. Can be used to determine a patient's responsiveness to bronchodilator therapy and in evaluating patients with neurological or neuromuscular diseases that affect breathing. Can be used for testing bronchial reactivity through provocation testing	None	Approximately 60-90 minutes of web-based training for healthcare staff to use the technology supported by reading IFU and downloading the application videos without external training. Additional onsite training is available.	GoClinic application comes pre-installed on the supplied tablet.	Data processed and can be stored online in a UK based Amazon Web Service cloud server which meets GDPR privacy regulations and industry standards for data security and protection. Data can be pushed or pulled to an EHR.	Training: >2,000,000 measurements have been collected from the MTI spirometry platform from patients with COPD, Asthma, ILD's, Cystic Fibrosis & neurological diseases that affect lung function that are reviewed to modify the technology and build algorithms as part of ongoing continuous improvement
NuvoAir (NuvoAir)	Spirometer (including firmware) is intended to perform basic lung function and spirometry testing	Heart attack within 1 week, Low blood pressure or severe high blood pressure, Abnormal heart rhythm, Unstable heart failure, Eye surgery within 1 week, Sinus surgery or middle ear surgery or infection within 1 week, Thoracic, Abdominal or Brain surgery within 4 week, High, uncontrolled, blood pressure in the blood vessels that supply the lungs, Collapsed lung, Clinically unstable blood clot in the lung, Recent concussion with continuing symptoms, History of fainting or passing out that is related to forced expiration	Long term respiratory conditions such as asthma, COPD and cystic fibrosis	Improvements to the spirometry algorithm may fall in the next 6-12 months and potentially some UX design changes.	NuvoAir provides training on the web-based portal to clinicians which allows user to see live data and download reports.	App installation on device available on Google Play or Apple Store.	Data is transferred for storage and online viewing to a secure cloud storage system. The cloud storage uses industry standard protocols and encryption to transmit data securely and store data securely at rest.	Not applicable - ruled-based technology (no use of AI-based algorithms)

Device (Company) [Previous Name]	Intended Purpose	Contraindications	Disease Identification	Planned changes or updates	Training Requirements	Installation methods	Patient Data	Algorithm training and validation data
		and/or cough, Brain aneurysm, Active or suspected transmissible respiratory or systemic infection, including tuberculosis, Physical conditions predisposing to transmission of infections, such as coughing up blood, significant secretions, or oral lesions or oral bleeding, Late-term pregnancy						

Appendix C2: Additional cost breakdown

Technology	Purchase option	Cost	What is included	Hardware costs	Integration	Training Time	Training Cost	Staff time
Standard care	-	-	-	Spirometer: £1,285.81 (source: £1,174.13 from NG245 inflated to current price year). Assumed used by 2100 patients during spirometer lifetime. Spirometer bacterial filter and mouthpiece: £1.16 (source: £1.06 from NG245 inflated to current price year)	Calibration costs: £0.13 (source: £0.12 from Table 20 NG245 inflated to current price year)	-	-	Measurement: 30 minutes practice nurse B5 with qualifications, £53 per hour (Jones et al. 2025): £26.50 Interpretation: 10 minutes practice nurse, £53 per hour (Jones et al. 2025): £8.83
ArtiQ.Spiro (Clario)	Annual software licence with 3rd party hardware	£3.00 per test (excluding VAT)	Support	Vitalograph pneumotrac spirometer with Spirotrac software: price £1,614.99 (excluding VAT). Medchip SpiroConnect spirometer: price £1,290 (excluding VAT). Note: Items are 3rd party and not provided by company, prices taken from supplier website 16/09/2025. The EAG assumed an average cost: £1,452.50. The EAG assumed that this would be used by a total of 2100 patients over the lifetime of the device (in line with assumptions made in NHS245, 2024). Additional costs associated with calibration syringe, bacterial filter plus mouthpiece will apply.	No extra cost charged by company	15 minutes with training manual Additional one-time session for interpretation report as needed (maximum 30mins)	Included Optional: ICB -wide installations onsite training and installation at a one-time cost of £250/practice	Measurement: 25 minutes practice B5 qualifications, £53 per hour (Jones et al. 2025): £22.08 Interpretation: 5 minutes practice nurse, £53 per hour (Jones et al. 2025): £4.42
LungHealth (LungHealth)	Annual software licence (diagnostic spirometry module)	£15.00 per patient (minimum volume 1,000 patients per ICB or Healthboard). Additional discounted costs were provided for 2- and 3-years contracts.	Software downloaded onto GP clinical system or Diagnostic Hub Computer System. Reports returned directly to the patients GP via GP clinical system Reporting Dashboard. Unlimited on-line training (including videos) Helpline (including technical support) 0900-1700 Monday to Friday. E-mail for additional support/queries if required.	Requires spirometer; assumed same as standard care.	Integration costs depend on locality requirements (max £5,000 per centre).	Overview of the GOLD guidelines: slide show with in-built learning assessment (1 hour). Online training videos demonstrating the functionality of the software (30 minutes). Access to test site, for users to gain experience of navigating through the software (1.5 hours; variable).	Inclusive	Measurement: 30 minutes practice nurse B5 with qualifications, £53 per hour (Jones et al. 2025): £26.50 [Relies on existing spirometry measurement]Additional consultation time (to go through questions, including interpretation): 20 minutes practice nurse: £17.66.
MIR Spiro (Medical International Research, MIR)	One off hardware purchase	NR	NR	Requires compatible MIR spirometer. Assumed average of 4 devices (MIR Spirobank II Smart, MIR MiniSpir PC based, MIR Spirobank Advanced hand held, MIR SpiroDoc Handheld) on NHS Supply Chain ([redacted]). The EAG assumed that this would be used by a total of 2100 patients over the lifetime of the device (in line with assumptions made in NHS245, 2024). Calibration syringe (3L): [redacted](NHS Supply Chain). Additional costs associated with calibration syringe. Bacterial viral filter average: [redacted] (NHS Supply Chain).	NR	NR	NR	Measurement: 25 minutes practice B5 qualifications, £53 per hour (Jones et al. 2025): £22.08 Interpretation: 5 minutes practice nurse, £53 per hour (Jones et al. 2025): £4.42

Technology	Purchase option	Cost	What is included	Hardware costs	Integration	Training Time	Training Cost	Staff time
EasyOne Connect (NDD)	NR	NR	NR	[redacted] NHS Supply Chain EasyOne Air handheld; assumed used by 2,100 patients during spirometer lifetime. Consumables (flow tube) [redacted] (NHS Supply Chain, assuming box of 200 bought each time)	NR	NR	NR	Measurement: 25 minutes practice B5 qualifications, £53 per hour (Jones et al. 2025): £22.08 Interpretation: 5 minutes practice nurse, £53 per hour (Jones et al. 2025): £4.42
GoSpiro (Monitored Therapeutics)	One off hardware purchase	Hardware: £3469.31 (converted $4999 provided by company to GBP). EAG assumed that this cost was spread across 2,100 patients (based on assumption from NG245 where 2100 patients assumed over 7-year device lifetime). Annual license and maintenance fee: £624.60 (converted $900 provided by company to GBP). EAG assumed that this cost was spread across 300 patients per year (based on assumption from NG245)	Platform for clinics, physician offices, traveling nurses, etc. Includes: GoClinic Tablet Case, GoClinic Case, GoSpiro	Hardware costs included in costs. The EAG assumed that this would be used by a total of 2100 patients over the lifetime of the device (in line with assumptions made in NHS245, 2024). Additional costs associated with calibration syringe. Filter and noseclip £242.90 ($350 provided by company) per box of 100.	Stated that if integration into an electronic health record is required, IT resources at the destination server will be required, as will be some additional cost by MTI IT personnel. However, no costs provided.	One web conference (1.5 hours for 5 participants)	£312.30 (converted $450 provided by the company to GBP) Note: Onsite training is also available at $2,000 for 5 participants for 3 hours. Travel and expenses for onsite training are not included (described as a "pass-through cost". Shipping and handling is also stated as a "pass-through" cost	Measurement: 25 minutes practice B5 qualifications, £53 per hour (Jones et al. 2025): £22.08 Interpretation: 5 minutes practice nurse, £53 per hour (Jones et al. 2025): £4.42
NuvoAir (NuvoAir)	NR	£149 (excl. VAT) per patient, per assessment (2-week assessment conducted at home; disease agnostic)	• Air Next Spirometer with pre-calibrated turbines delivered to patients' home. • Access to NuvoAir Home App for duration of assessment (2-4 weeks). • Triage and Onboarding appointments with a NuvoAir Physiologist (ongoing support, coaching and training). • 2 - 4 weeks of physiologist monitoring and coaching as required, including app-based feedback based on an algorithm for spirometry quality and interpretation. • Fully interpreted Respiratory Data Insights Report sent back to referring clinician using relevant guidelines and key data insight. • Access to NuvoAir Clinical Portal for Clinicians • Regular remote clinical discussions with site and NuvoAir Team	Company stated that no maintenance costs is required. Patient retains spirometer. Company covers cost of the return of the spirometer if clinical service requests	Company stated that no software installation is required.	NR (provided remotely by Physiologists and NuvoAir team)	Inclusive	Measurement: N/A Interpretation: N/A

Appendix D – Correspondence log

Appendix D1: Questions to Experts 11 September 2025

Expert contact details and declarations of interest:

Expert #1	[redacted]
Expert #2	[redacted]
Expert #3	[redacted]
Expert #4	[redacted]

Availability of spirometry:

1. What proportion of GP practices perform spirometry in England?

Expert #1	[15/09/2025] About ⅓ of GPs. Asthma and Lung UK did a useful piece on spirometry access including ARTP accreditation, https://www.asthmaandlung.org.uk/healthcare-professionals/ics-respiratory-review/spirometry#:~:text=SDSmyhealthcare%2C%20one%20of%20the%20GP,Cambridgeshire%20+%20Peterborough
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Unsure, with the establishment of CDCs and diagnostic hubs, I would say it is low, unless the hub or community spirometry contract sits within the GP confederation.

2. What equipment, staff, training and accreditation is needed? Does this vary by size of practice?

Expert #1	[15/09/2025] Accredited by the ARTP (though this is uncommon). Access to a spirometer +/- software on the computer, filters, nosepegs. This will be implicated by practice size, and likely if there is a respiratory interest in the practice
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Equipment would be an approved spirometer and FeNO, would need consumables for tests, software to import into patient records, ability to measure height and weight. For spirometry need ARTP certification for either performing, interpretating or both (ideally), for FeNO nil certification, however competence might be measured locally. Amount would depend on service.

3. Transition to test: idea of waiting times for patients undiagnosed waiting for objective testing?

Expert #1	[15/09/2025] In GP practice could be up to 6 weeks, in secondary care can be as long as 6months
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Varies, in some areas they still do not have access to diagnostic spirometry and FeNO, should be in line with Service specification 4 weeks from referral, however in practice that is very challenging with some waiting times, I believe up to 12months.

4. How many patients would a typical GP practice see for spirometry (for diagnosis) per year?

Expert #1	[15/09/2025] ICBs report between 2000-20000 per year, so approx 13-130 patients per surgery.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Depends on current vs expected prevalence, size of GP surgery and other risk factors – smoking prevalence, environmental risk factors, deprivation in area. Locally rates are between <5 referrals in 2 years, to over 300 referrals. Average 74 referrals per practice.

Community Diagnostic Centres (CDCs):

5. What proportion of GPs refer to a CDC for testing?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] I wouldn't know that, we do not run a CDC.

6. Can we assume equipment, staff, training etc are broadly the same between GP and CDCs?

Expert #1	[15/09/2025] Yes, may have better access to accredited staff
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] CDC likely have access to more diagnostic equipment, with ability to do full lung function.

7. Transition to test: idea of waiting times for patients undiagnosed waiting for objective testing (same as GP)?

Expert #1	[15/09/2025] Approx 6weeks
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Unable to answer, depends on CDC capacity.

8. How many patients would a typical CDC see for spirometry (for diagnosis) per year?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Unsure, as do not run or link in with a CDC

Home spirometry:

9. If spirometry is done at home, is this by the patient alone or with a healthcare employee?

Expert #1	[15/09/2025] Ideally with a HCP, but some companies propose this can be done alone

Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] In the UK, I would say by HCP. However, home testing by patient, might be available in some areas that have a large locality.

10. Transition to test: idea of waiting times to have kit to test at home?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Do not offer, so wouldn't be able to comment.

11. How many patients would have spirometry (for diagnosis) at home per year?

Expert #1	[15/09/2025] I would expect in adults this would be a small sample
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Do not offer, so wouldn't be able to comment.

Secondary Care:

12. What proportion of patients would be referred from a GP to secondary care for spirometry for diagnosis without having spirometry attempted in primary care?

Expert #1	[15/09/2025] I'd estimate perhaps 10%. Though the ALUK data shows a significant number of surgeries with no provision of spirometry so all these will go to CDC or secondary care
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Depends on pathways, in NEL GP cannot refer directly for lung function. Access would only be via a Secondary care referral.

13. Costs in secondary care? Can we assume a single respiratory outpatient appointment?

Expert #1	[15/09/2025] Yes
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Would be NP appointment with consultant and then cost of Respiratory Diagnostic appointment, then follow up for review of results. However, this is likely on block in most Trusts.

14. How long would they wait to be seen in secondary care?

Expert #1	[15/09/2025] 6months, some waiting lists are as long as 12 months
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Depends on the Trust, cannot give an average. Locally could be 12 weeks (excluding 2WW), however nationally varies.

General:

15. Do these proportions referred (from GP to CDC, secondary, home) differ for adults and children?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] No response

16. Do the above proportions referred (from GP to primary, CDC, secondary, home) differ by disease (asthma, COPD, restrictive lung disease)?

Expert #1	[15/09/2025] Possibly more likely to be referred if you have asthma- provision of reversibility testing is less likely than routine spirometry
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] No response

17. Do wait times differ for adults and children?

Expert #1	[15/09/2025] I would expect so but I couldn't estimate children wait times.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Yes, lower for Paediatrics locally, cannot comment on nationally, although access to Primary/Community diagnostics for paediatrics is not available everywhere.

18. Do wait times differ by disease (asthma, COPD, restrictive lung disease)?

Expert #1	[15/09/2025] Not usually
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] No, not locally anyway.

19. What proportion of patients would obtain a diagnosis without spirometry (spirometry not used):
    a. Asthma?
    b. COPD?
    c. Restrictive lung disease?

Expert #1	[15/09/2025] More likely in Asthma and COPD. Often diagnosed by clinical history- estimate perhaps 10% do not receive any spirometry- maybe more. Unlikely in restrictive lung disease.
Expert #2	[19/09/2025] No response

Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Asthma - 25% (locally) Nationally higher around 50% from recent conference data. COPD: <10%, only confirmed on CT if not by spirometry

20. Is there any published UK audit data that would help quantify any of the above?

Expert #1	[15/09/2025] https://www.asthmaandlung.org.uk/healthcare-professionals/ics-respiratory-review/spirometry#:~:text=What%20the%20data%20shows,volume%20may%20not%20be%20accurate.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] I am sure there is, just not 100% sure

21. Assume in model that value can be added by changing waiting times for testing, accuracy of testing result and cost of testing (different banding of staff involved in interpretation). Are there any other key benefits/features of the technologies listed in the scope that needs to be captured in the economic model structure?

Expert #1	[15/09/2025] Accuracy in different demographics i.e. ethnicities where they are under-diagnosed.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] No response

In asthma diagnosis, guidance states that in the absence of spirometry, peak flow over a couple of weeks can be used instead:

22. Is this what would happen in practice or would the patient be referred for spirometry elsewhere?

Expert #1	[15/09/2025] I expect this is frequent. It is often easier and cheaper and does not require technical certification.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response

Expert #4	[29/09/2025] Yes, PEFR monitoring for 2 weeks would be recommended as per national guidelines, with a variability of 20%

23. Is spirometry test and result (and additional test and results) feasible within a 1-month time cycle?

Expert #1	[15/09/2025] Yes
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Yes

24. We haven't modelled an option for testing other than spirometry to be unavailable (NICE Guidance suggests that only spirometry is expected to be unavailable and need an alternative), is this appropriate?

Expert #1	[15/09/2025] Yes
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Yes

25. For people aged 16 years and older with suspected asthma, what proportion of patients are given a provisional diagnosis and receive treatment while waiting for spirometry?

Expert #1	[15/09/2025] 60-80%
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] In our centre, approximately 40%

26. For people aged between 5 and 15 years with suspected asthma, what proportion of patients are given a provisional diagnosis and receive treatment while waiting for spirometry?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Locally 40%

27. For people with suspected COPD, what proportion of patients are given a provisional diagnosis and receive treatment while waiting for spirometry?

Expert #1	[15/09/2025] 30% perhaps
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] 30% in our centre

Test failure:

28. Is there a failure rate associated with implementation of the technologies listed in the scope, that is, would the technology ever fail to work correctly and therefore leave the patient relying on standard care for their diagnosis?

Expert #1	[15/09/2025] Failure rate would refer to the interpretation. I expect the equipment doesn't vary greatly to routine spirometry.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Lower risk, however, always possibly.

29. If it failed, would the test be repeated straight away? Would additional costs/time be incurred for this repeated test?

Expert #1	[15/09/2025] Depending on access to equipment- you may be able to use the results but interpret them independent of the technology, in which case no repeat necessary. Otherwise they are likely to be able to repeat immediately (unless at home)
Expert #2	[19/09/2025] No response

Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Test would be reported as is, any further testing would be another appointment.

30. Tests concurrent to spirometry: For COPD, guidance recommends additional investigations when needed. In what proportion of patients would the following be done:

    a. Sputum culture

Expert #1	[15/09/2025] <10%
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] depends on symptoms, not routine unless productive of sputum

    b. Serial home peak flow measurements

Expert #1	[15/09/2025] <5%
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] common for asthmatics, in monitoring symptoms, as part of asthma action plan.

    c. ECG and serum natriuretic peptides

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] only if unless indicated.

    d. ECG

Expert #1	[15/09/2025] Best practice they would all have an ECG but probably 30%

Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] unsure, do not refer for. Would be only if indicated. I would say <20%

e. CT of the thorax

Expert #1	[15/09/2025] 40%
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] if indication to, particularly those with unexplained cough/symptoms or on a 2WW pathway.

f. Serum alpha-1 antitrypsin (and in what proportion would an onwards referral to a specialist centre be made)

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Once confirmed diagnosis of COPD, young age. Locally would say <1% of patients.

g. Transfer factor for carbon monoxide

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] likely most referred for lung function in secondary care.

Further testing if spirometry is not available:

31. In what proportion of adults being investigated for asthma would a referral need to be made for bronchial challenge test?

Expert #1	[15/09/2025] No response

Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] The results of this study when they are available should help answer this question Rapid Access Diagnostics for Asthma (RADicA): protocol for a prospective cohort study to determine the optimum series of investigations to diagnose asthma using conventional and novel tests - PubMed. I speak to [redacted] and [redacted]Manchester) quite often and I understand from them that, based on preliminary data from the RADiCA study, around 26% of adults who receive a diagnosis of asthma only have objective evidence of asthma based on bronchial challenge testing and no other tests. This report might also be helpful to you (although I expect you will already be aware of it): NG245 Asthma: Cost-utility analysis: Most cost-effective sequence or combination of tests to diagnose asthma
Expert #4	[29/09/2025] Less than 5% in our centre

32. What proportion of children with suspected asthma would have skin prick testing to house dust mite?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Due to manage paediatrics, so unable to answer

33. What proportion of children with suspected asthma would have total IgE and blood eosinophil count measured?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Due to manage paediatrics, so unable to answer

34. Would children ever have both options above?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Due to manage paediatrics, so unable to answer

35. Would a patient misdiagnosed with asthma or COPD, and therefore undergoing incorrect treatment, experience a decline in their quality of life associated with this? How long may this last?

Expert #1	[15/09/2025] Unlikely as a result of treatment unless they experience inhaler side effects.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Yes this could happen. Depends how long the condition is misdiagnosed and not limited they have become by this. If it has lead to a reduction of function, being unable to work, loss of muscle mass/strength/exercise tolerance, it could take a long time to recovery, if they do at all.

Questions on Markov model – pre-diagnosis and management:

36. Asthma guidance for adults states first line testing is blood eosinophil count or FeNO. Are these mutually exclusive, or would some patients have both?

Expert #1	[15/09/2025] Some would have both.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Normally repeat BEC due to differential diagnosis and/or FeNO

37. What criterial would be used to choose which test (is FeNO used to rule in asthma and blood eosinophil count used to rule out asthma)?

Expert #1	[15/09/2025] FeNO should be prioritised over eosinophils. Eosinophils would not be diagnostic (i.e. non-eosinophilic asthma is a diagnosis)
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Both could be used for both reasons in practice, with BEC concern is could be misleading therefore often FeNO used to confirm.

38. What proportion would have each test? Is it correct to assume these tests both take place in primary care?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] BEC normally 100% have had a FBC at some point (adults) Paeds very few, FENO attempted with all. Paediatrics – <2% have been not been able to perform, adults approx. 10% have struggled to perform.

39. What proportion of patients, in total, are diagnosed at this stage and do not go on to have spirometry?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Depends on service, locally <25%, however some services around 50%.

40. We have assumed that a patient who has an exacerbation will be diagnosed as a result of that and will not return to an undiagnosed or testing state. Is that appropriate?

Expert #1	[15/09/2025] That commonly occurs but they should be diagnosed during a stable state.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] No, probably diagnosis can be given prior to testing, however diagnosis should still be confirmed with one of the recommend objective tests and a clinical history that fits. Not all wheezy patients, who might have a course of prednisolone will have asthma and not everyone smoker with a chest infection will have COPD.Confirmation of airflow obstruction that is either reversible (asthma) or non reversible (COPD) is important.Or evidence of type 2 inflammation (asthma)

41. We have assumed that an exacerbation would lead to a trip to hospital, either only for treatment in A&E or then resulting in an inpatient stay.
    a. Is this appropriate or would an exacerbation be treated in any other settings?

Expert #1	[15/09/2025] Mild exacerbations could be treated at the GP surgery
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] For moderate asthma exacerbations, they might be managed by a acute respiratory infection virtual ward, hospital at home team, community respiratory team, or possibly primary care (depends on the local urgent care pathway)

b. What proportion of exacerbations would be seen in A&E only?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Max 65% would stay maybe up to 24hrs within A&E observation unit if required

c. What proportion would result in an inpatient stay?

Expert #1	[15/09/2025] 2 days
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] 35-40%

d. Would this differ for COPD?

Expert #1	[15/09/2025] Average is much higher (8days) but this includes severe COPD and long established diagnosis.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Due to VW and early supported discharge programmes, 1-3 days, excluding those who require ITU.

42. In general, is this model structure appropriate for asthma and COPD and restrictive lung disease? We can switch off transitions and states, but need to consider whether additional states are needed?

Expert #1	[15/09/2025] No response
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] No response

43. We have assumed that after diagnosis that a patient will enter the either a partially controlled or fully controlled state (both with medication provided). Whereas those with the disease but testing negative will enter an uncontrolled state (no medication but higher risk of exacerbation and death). Is this simplification appropriate?

Expert #1	[15/09/2025] Assuming this refers to confirmed diagnosis by spirometry or other test. There will be a proportion of patients diagnosed by clinical history only and receiving treatment when it is not indicated.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] That isn't aligned with guidelines, further objective testing would result, if someone had a strong clinical history of asthma and symptoms, then recommendation would be to treat, while confirming diagnosis. Negative spirometry with asthma, is common, especially if already on treatment and washout period of treatment would be longer than the time that patients are told to withhold before testing.

44. We have assumed the transitions between Controlled, Partially Controlled and Uncontrolled will follow a linear path backwards and forwards to reflect gradual worsening and improvement of symptoms, and that transitions directly from controlled to uncontrolled would reflect a stopping of treatment. Is this appropriate?

Expert #1	[15/09/2025] No, stopping treatment is unlikely. Treatment would stay the same. Likely no changes during reviews and or not describing intolerable symptoms.

Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Yes and no, stopping treatment might not be the only explanation that symptoms become uncontrolled. Exacerbations, seasonal triggers, co-existence of other health conditions, could all alter the control of a disease.

45. We have assumed that an exacerbation can occur from any level of control but likely rarer the more controlled the condition is (in line with previous economic modelling), is that appropriate? How often would you expect an exacerbation in someone in each of the three states?

Expert #1	[15/09/2025] In copd the average per year is 2. but these will be worse with uncontolled symptoms- but they would be on medications so I am not sure “controlled” and “uncontrolled” are appropriately defined.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Yes, symptom/disease control is related to risk of exacerbation. Higher risk in those with lower control, and you would expect regular exacerbations. In someone with good control, they may not exacerbated or max 1 per year.

46. Are you more likely to have a second exacerbation if you have had a first exacerbation? Is it appropriate, for our modelling, to assume that exacerbation risk is the same regardless of prior exacerbations? Would there be any lasting effects on quality of life after exacerbation that needs to be considered or might change with repeated exacerbations?

Expert #1	[15/09/2025] Yes, much more likely. 30 day readmission in copd can be as high as 30%. There will be implications on QoL. COPD patients should receive pulmonary rehabilitation as a result because they can expect worse HRQoL, exercise capacity and symptoms such as breathlessness. The more frequent = the worse QoL generally speaking.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] Repeated exacerbations can result in airway remodelling and progressive irreversible decline in lung function (Bai et al. 2007)

Expert #4	[29/09/2025] No, some people have one exacerbation, are reviewed and greater control is gained. Others have multiple exacerbations. Risk of exacerbation is higher the more you have. Yes quality of life can reduce post exacerbation and patients can start from a lower baseline the more exacerbations they have, after each.

Other questions:

47. Do existing spirometers available to the NHS have settings whereby feedback can be given to determine whether the results are within normative ranges based on clinical guidelines? If so, what proportion of services use these spirometers?

Expert #1	[15/09/2025] Yes most spirometers do this
Expert #2	[19/09/2025] From my experience of NuvoAir and Spirobank Smart they do vary slightly on this point. Although from the patient side - they tell you what your spirometry is in %. With NuvoAir is gives you the % of what it is compared to the normative range (based on height, weight, etc) and also the figures - it also gives the normative range figures so that you can see where you sit. Although it doesn't give you detailed feedback, it does give you feedback on where your lung function sits. The Spirobank Smart also gives you the predicted values - but I think the Spirobank has more features and is more intuitive. I understand that on the clinical side of both NuvoAir and Spirobank Smart, there may be more feedback given - but for the patient it is more about presenting the % and figures (from my experience).
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Yes, most diagnostic services would use a spirometer that provide this information.

48. What feedback do existing spirometers offer to identify where a test has not been performed adequately, either because of human or technical error?

Expert #1	[15/09/2025] Most can determine if the effort was appropriate, and determine quality control (i.e. tests within 10% variance).

Expert #2	[19/09/2025] The NuvoAir does give you a 'grading' for your test for both FEV1 and FVC, however from the patient side - it doesn't say why it was given that grade. I think it is on the clinical side of the app/dashboard that a professional can then see why and interpret why it was given that grade - for example, the patient took an extra breath during the test. I have seen that sometimes the app doesn't connect to the NuvoAir, so you may sometimes think you have but due to technical error, the test doesn't work. With the Spirobank Smart - from my understanding it does also provide session grading, but I think it might be on the clinical side where you can see why the patient was given that grade.
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] The newer models will do this, the older models may indicate good vs poor blows, but might not be able to identify the exact technical error.

49. If inadequate, would the measurement be repeated straight away? Is there a financial consequence (e.g., extra 1 minute of staff time)?

Expert #1	[15/09/2025] Straight away, unless patient unable.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Yes would be repeated within the appointment time. Nil financial implication, unless the patient performs max number of blows, which is 8 or is unable to do the test, in that another appointment would be booked, which will come at a financial cost to some services, if tariff based.

50. Is 'post-bronchodilator spirometry' the same thing as 'bronchodilator reversibility with spirometry'? (The first is referred to in COPD guidance and the second is referred to in asthma guidance)

Expert #1	[15/09/2025] Yes
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response

Expert #4	[29/09/2025] Yes, interchangeably used

51. Terminology: what is the most appropriate way to classify lung conditions? For example, the term *condition* is used by some interchangeably with *disease*, but in other documents *disease* is strictly *restrictive* or *obstructive*. Is there a preferred terminology to describe asthma, COPD and restrictive lung conditions/disease?

Expert #1	[15/09/2025] I would consider these interchangeable but perhaps patients have a preference.
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Both are used, groups of disease – obstructive/restrictive, if disease name is used, then it would be the same for both those under obstructive (COPD/Asthma) and those under restrictive (ILDs). It is most appropriate to classify by disease.

52. The focus on this assessment is on the technology's value for diagnosis of lung conditions. The EAG will however look at populations with an existing diagnosis for evidence for diagnostic accuracy. Do you think that the following outcomes could also be comparable in using the technologies with people who have an existing diagnosis (such as COPD, asthma):
    a. Clinician usability, views and satisfaction?
    b. Patient usability, views and satisfaction?
    c. Time to perform and interpret spirometry?

    Are there any other outcomes in the Final Scope that the EAG should consider in populations where an existing diagnosis is made?

Expert #1	[15/09/2025] Yes all these should be comparable to undiagnosed
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] a – Yes, b- Yes, c- Yes

53. Is there any UK routinely collected data (registry data), service evaluations or audits of the diagnostic pathway that you are aware of that would support our assessment (and economic model)?

Expert #1	[15/09/2025] NRAP COPD audit records exacerbations etc but not diagnosis pathway specifically
Expert #2	[19/09/2025] No response
Expert #3	[24/09/2025] No response
Expert #4	[29/09/2025] Only aware of ICB level work, there is no routine registry, the higher-level data I believe is about tests performed, rather than tests vs disease diagnosis. An area for more work to be done.

Thank you very much for your time and expertise.

Appendix D2: Minutes from meeting with Experts 12 September 2025

GID-HTE10065 Lung Function EVA
EAG meeting with Experts
12 September 2025 @ 10:00-11:00
Microsoft Teams

Invited:
EAG: Emma Belilios [EB], Kim Keltie [KK], Rachel O'Leary [RO], Rosalyn Parker [RP], Ryan Kenny [RK]
SCMs: Peter Saunders [PS]
Experts: Gillian Doe [GD], Sherif Gonem [SG], William Man [WM],
EAG Expert: Kay Wang [KW]
NICE: Sophie Harrison [SH], Martin Njoroge [MN]

*Apologies: Enya Daynes [ED, **SCM**], Laura Beattie [LB, **lay SCM**], Laura Graham [LG, **Expert**], Terri-Lynn Quigley [T-LQ, **lay SCM**]*

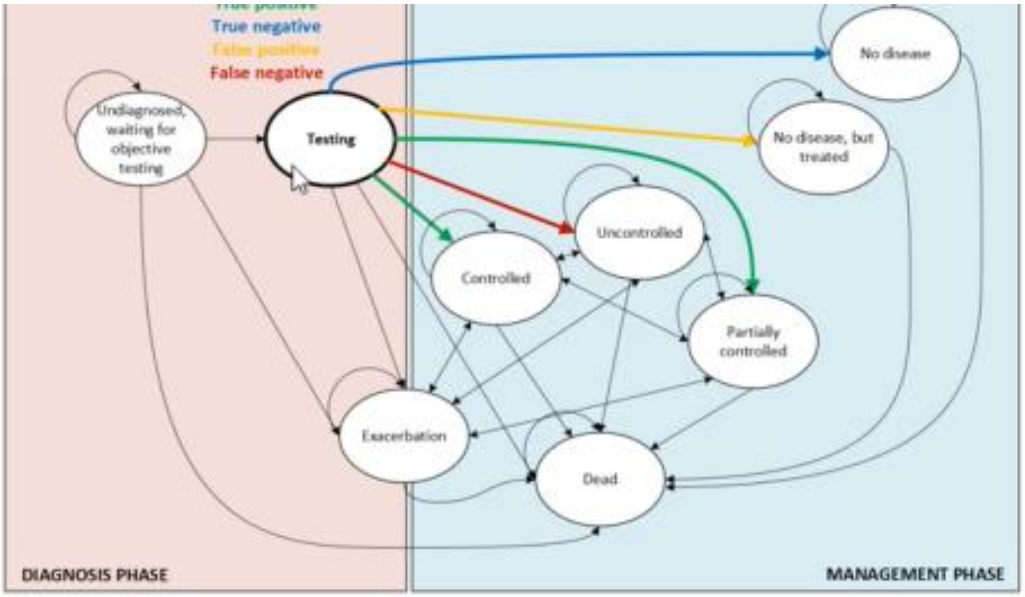
Welcome and introductions

Background
EAG will be looking at the clinical and cost-effectiveness of the technologies included in the Scope of this EVA. Main aim of today is to discuss the structure of the conceptual economic model and the assumptions that the EAG is considering.

The EAG may also discuss some of the approaches planned in terms of handling the clinical evidence and appropriateness of these.

[RO] – have taken a Markov model approach – need this to capture impact on waiting time. So there is a Diagnosis phase, then a Management phase (decision tree structure). For the 'undiagnosed' population we assume those

suspected of having asthma have already had FeNO and blood eosinophil testing, so are just waiting for spirometry. From this state, the patients can die or they can suffer an exacerbation that needs urgent or emergency treatment, or, they move into the testing state.



So, we assume that if they have an exacerbation while they're in the undiagnosed state or in the testing state, they would then be diagnosed by some of the means and they wouldn't return to that testing pathway. They would move straight into the management phase and it's the rate of transition between the undiagnosed and testing state that we'll be using to model the waiting time for spirometry. We've assumed that pre spirometry testing incurs the cost equally in both arms and it'll diagnose the same proportion of the starting population and doesn't need to be modelled.

‘Prevalence of disease’ is the prevalence of asthma in those that have not had a diagnosis after initial testing, not the prevalence of asthma in the general population

Then move onto decision tree – testing state. We start by splitting the population into whether they have disease or don't have the disease. In each of those two arms we’ve then got whether or not spirometry is available. If

spirometry isn't available, we move into an alternative test which could be positive or could be negative. If it's negative, there's an option of a further test which would then be used to make the final diagnosis. If spirometry is available, we've got three options from this, either it is positive, it is negative, or the result is unavailable. And that could be that the AI or algorithm is unable to provide an interpretation, so no result is available that way, or it could be that the patient is unable to perform the spirometry test at all. And then we've got the same options from there that if spirometry is negative, there is the option of the further test. And if the result is unavailable, there would be an alternative test leading into possible further test.

[PS] – if a patient has an exacerbation they may still go on to have testing, particularly in asthma, as there are some 'mimics' (conditions that may cause asthma symptoms but are not asthma). They are more likely to be seen in secondary care at this stage, but it is possible that they will still be under GP care. Normally we wouldn't class an exacerbation as definite proof you've got the disease because it's an exacerbation of symptoms usually rather than exacerbation of disease.

[RO] – agree, not definitive, but testing might look different? We have assumed that all exacerbations would be seen in the Emergency Department and may need inpatient stay, does that seem reasonable? Or are there exacerbations that are less severe and therefore handled elsewhere? **[SG]** – No, not all seen in secondary. About half (depending on disease) would be seen in primary care (COPD exacerbations more likely to be managed in primary care than asthma).

[GD] – exacerbations will impact on waiting times. Have to be stable (typically 6 weeks after an exacerbation) to have testing. Depending on whether you've been prescribed medication. If the model is specifically about timing that little extra loop where they go back in might need a little bit of thought.

[KW] – from a primary care perspective, a lot of exacerbations are misdiagnosed as chest infections. It might be when people are presenting regularly with ‘chest infections’ requiring antibiotics that an underlying condition would be suspected. I just wanted to bring that up in case there was somewhere you could factor that into your model because that's not an uncommon situation.

[KW] - The assumption that everyone waiting for spirometry testing will already have had FeNO testing is incorrect. The FeNO rapid uptake programme a few years back estimated that only about 53% of primary care networks had access to FeNO testing at that point. That may be lower now because the rapid uptake programme didn't provide any kind of ongoing funding or support for people to continue testing. So, either they had to find that support some other way or they might have stopped testing. So certainly I don't think it's necessarily everybody would have access to FeNO testing prior to spirometry testing. And if access is via Community Diagnostic Centre, which provides both spirometry and FeNO, a lot of clinic patients would refer for both at the same time because that's a more efficient way of getting things done. **[RO]** – can you assume all will be waiting for spirometry**. [KW]** – Probably yes, everyone is likely to have access to blood eosinophil testing and would probably have this, though might be referred for both at the same time if available. And it gives them a more complete picture from the outset about what the patients’ airways are like. So that if they do instigate some treatment and the patient doesn't respond, they've got a better idea of why that might be.

[RO] – is it OK to assume that everybody in that undiagnosed state at the start is waiting for spirometry?
[KW] - I don't think so necessarily, because blood eosinophils is something which everybody can do. So there's no reason why you would withhold that or decide not to do it. And FeNO is also a much easier test and for patients to do than spirometry, and the result is more reliable. So if people have access to one or both of those tests they would probably do them.

[RO] – At the end of the diagnosis phase, people move to Management phase (although focus is on diagnosis, need to understand what happens next to assess economic impact).

The tree splits the population of people with symptoms who need objective testing for lung conditions into those with disease, and those without. If spirometry is available for the patient to have, they have it, with the possible outcomes of a positive test, negative test, or no result available (for example, test not performed correctly, AI or algorithm cannot provide interpretation). If spirometry is not available, or if no result is available, for asthma, an alternative test (serial peak flow measurement) is offered, which may be used to diagnose. If these tests are negative, there is one final testing option. For asthma, this is bronchial challenge test for adults, and skin prick testing to house dust mite or total IgE and blood eosinophil count for children. Each patient can only pass through the testing state once, so at the terminal nodes of the tree, patients end up with one of four outcomes:

1. They have the disease and are treated (**true positives**)
2. They have the disease and are not treated (**false negatives**)
3. They do not have the disease but are treated as if they do (**false positives**)
4. They do not have the disease and are not treated (**true negatives**)

From here, patients move into the management phase of the Markov model. To account for the likelihood of an imminent exacerbation in the false negative group, they move into the uncontrolled state. Any costs incurred by being in this state will be negligible because of the high rate of transit to the exacerbation state. Those who have a true positive diagnosis are split between the controlled and partially controlled states. Those with false positive diagnoses will move into the "no disease, but treated" state, incurring costs for management of a lung condition they do not have, and receiving the utility decrement associated with unnecessary treatment (potentially inhaled steroids). True negatives move into the "no disease" state, incurring no costs or utilities. Any further testing needed for this group, if they remain symptomatic, is beyond the scope of this EVA topic. For both of these states, patients remain there until death.

[RO] – Split people with a positive spirometry result between controlled and partially controlled. False positive – no disease but treated state – utility decrement applied (receiving unnecessary treatment). True negatives – no costs or utilities, unless further testing is required.

Wiil be relying on the published evidence to work out transitions

Assume if you go from controlled to uncontrolled you have stopped medication?

[SG] – don't think this is a fair assumption.

[KK] – all embedded within the testing stage. To truly look at cost effectiveness and uncertainties, need to look downstream to management once a diagnosis has been made. Can you go straight from controlled to uncontrolled? **[SG]** Correct, but may not be because patient stopped meds.

[WM] – challenging to say ‘disease’ or ‘no disease’. Lots of scenarios where you may have normal spirometry but disease, or abnormal spirometry, but no disease. Can take years to get to diagnosis, and often treatment happens in the meantime. Lung Foundation did some studies around this. We did a feasibility study, looked at GP practice notes and secondary care notes 6 months after spirometry and lots of people were still waiting for diagnosis.

For COPD, spirometry is a reliable diagnostic. More challenging for asthma. More than half of patients that end up in secondary care will have normal spirometry.
[KW] – why things might worsen, asthma is a dynamic condition, which changes in severity over time. Some people have triggers (hayfever, dust). Uncommon for people to stop their meds. People are often given inhalers early on and get quite attached. Poor adherence is an issue, but people tend not to stop completely. A lot of people who think they are well controlled are not. They think their symptoms are ‘normal’ because they have tolerated them for so long. Have also found that there is a high prevalence of multi-morbidity. About 60% of participants in an ongoing trial have a concurrent condition that may mimic asthma symptoms.
[RO]- do we therefore need to consider other conditions in the modelling?
[KW] – ideally, if symptoms are getting worse, should look at all possible causes including exacerbation of other conditions. In reality, patients may just get additional steroids.
[SG] – part of the difficulty with lumping respiratory diseases together is the pathways are different, spirometry role is different. Should maybe focus on COPD and asthma (airway disease diagnosis) only for this assessment. Restrictive lung disease is less common. **[RO]** agree, that’s what we are planning. Have tried to create the model which could be adapted for other conditions but will focus on asthma and COPD for this one.
[KK] – does the current model structure work for asthma and COPD? **[SG]**– yes. **[WM]** – might need to include a feedback loop. People with suspected asthma might be re-referred for testing multiple times.

[KK] – do we need another state, undiagnosed but receiving treatment? **[SG]** - yes, this is what happens in real life. **[WM]** – also, not just before testing – people without a conclusive diagnosis after testing may also be receiving treatment.

[PS] – note that there are still some people at the end who are uncertain in the model. This is good, this is reflective of real life. **[KK]** – can make sure this is clear in the report.

Questions/Discussion

Q) Availability of spirometry in primary care

[GD] – availability is really varied

[WM] shared BMJ paper https://bmjgroup.com/the-bmj-reveals-silent-scandal-of-missing-lung-tests-across-england/

ICS – provision - https://www.asthmaandlung.org.uk/healthcare-professionals/ics-respiratory-review/spirometry

[KW] – very complex, top line ,survey in Oct 2024, 42 ICBs, 34 responded, 27 commissioning spirometry in primary care.

Mixed model, includes CDCs, health clubs, lung health checks as well as GPs, only 5 with just GPs

Q) How many patients would a typical GP practice see for spirometry (for diagnosis) per year?– From the survey, 5,000 a year in one region with only GP provision

[KK] – 5,000 per ICB? **[KW]** – no, lot of variation, table at the end of the paper – massive range. Data are just not collected anywhere so all we have is the surveys.

[KK] – will need to calculate a' per patient' cost – can take mid point and extremes. Hope is that these techs will mean more people get spirometry, but what would this look like, what is the maximum that would be feasible? **[WM]** – not sure how AI technologies would increase throughput. Barriers are time taken to get the patient in. Benefits from the AI technologies are more likely to be around accurate diagnosis

[WM] – one study estimated that diagnosis time is 2/3 testing, 1/3 interpretation. If the AI technologies can cut the interpretation time, that would save GPs time. There are some abstracts, 10-15% reduction is about the ball park.
[KK] – will look at plausible ranges. Focus is on structure of the model. Will then need to share tables of parameters
[PS] – could potentially use less qualified staff (can take years to train) so that allows more of the tests to be done.
[KK] – one abstract suggested you could jump from B7 carrying out the test to B3 – would that be feasible? [**GD]** – does that mean carrying out the test only or also interpretation? **[KK]** not clear. **[GD]** – pre Covid, might be B7 practice nurse, but could be healthcare assistant. This might reduce time if you could have less specialist staff carrying out the tests, but think B7 is needed for interpretation.

Q) What equipment, staff, training and accreditation is needed? Does this vary by size of practice?
[SG] – most people carrying out spirometry will have done a course, and have a certificate, but could be practice nurse or HCA. Uncommon for physiologist (secondary care) to do tests in primary care. **[KW]** – some practices have a respiratory specialism. The quality of testing in primary care is therefore variable which leads to interpretation difficulties.
[WM] – Long term plan to improve spirometry testing was that everyone carrying out spirometry should have ARTP accreditation. There is a cost attached to this, and it takes time to get the accreditation. There was therefore pushback, many GPs found this unaffordable. So gold standard is ARTP accreditation, but doesn't often happen. AI technologies may support use of lower level staff to deliver quality spirometry is the argument. Asthma UK survey provides some detail.

Q) spirometry testing at home

[PS]– looked at this during Covid pandemic – works well in people who know how to do the test. For first line testing, need coaching and if you are having to do this online this takes time and money.
[KK] – So can we assume home testing is not suitable for this population?
[SG] – agree. We use home testing in severe asthma, but train in person first, patients don't go home with the device till we are confident they can use it properly. So, better as a second line test. **[PS]** – does anyone have experience of video training? **[RP]** – one of the technologies, NuvoAir is purely home based, but has onboarding included in the offer. Will be applied in specific situations.
[RP] – some patients can't get assured spirometry at home. Some of the technologies in scope can be used in multiple settings so for these, will focus on use in a clinical setting for this assessment.

[SG] – not sure a home spirometry service counts as AI. This should focus on AI interpretation of clinic based spirometry? **[SH]** – We broadened scope to include algorithms rather than pure AI. NuvoAir algorithm therefore is within scope. **[PS]** – all home-based spirometers have a bit of AI to judge quality of the output. **[WM]** – even basic clinic based spirometers have an algorithmic element. Majority, simple algorithm.
[KK] – 2 main questions. Focusing on diagnostic but need to see whole pathway (lifetime model) – how long should the cycle length be, and how many cycles should we run? Proposing 1 month cycles currently. But that now seems inappropriate (would unlikely to get through diagnosis in 1 month).What would work? 6 months? Might be different from diagnostic to management.
[SG] – 1 month sounds reasonable, then run 12 times (1 year).
[KW] – typically, would allow 4 weeks after treatment prescription to evaluate results, or maybe 6 or 8 weeks, but 4 weeks minimum.

Q) Are you more likely to have a second exacerbation if you have had a first exacerbation? Is it appropriate, for our modelling, to assume that exacerbation risk is the same regardless of prior exacerbations?

[SG] you are slightly more likely to have an exacerbation if you've had one before (around 15% will have another one). But about 90% will just have one.

Q) Model helps us to look at 2 value propositions – diagnostic accuracy and waiting time. Any other value propositions we need to be considering?

[PS] – think the main value is in monitoring response to treatment, but that's a different EVA.

[RO] Please can everyone share responses to the rest of the questions by email.

[KK] – not respiratory experts – everything is a simplification. So building the model to be controllable.

Next Steps

Some questions will likely be circulated during the process of the EVA and the EAG are extremely grateful for your support on this topic. Minutes from the meeting will be circulated for correction and added as an appendix in the EAR.

Any other business

There was no other business

Post meeting note:

E-mail received 16 September 2025 from Kay Wang, Clinical Professor in Primary Medical Care, University of Southampton:

Thank you for inviting me to join the EVA EAG group meeting last week.

Following the discussion, I have attached some references which I thought you might find helpful to give you some more accurate estimates of some of the assumptions we discussed:

Blakey et al. (2017) - this study examined routinely collected data from primary care medical records to estimate risk of future asthma exacerbations in people aged 12-80 years with a coded diagnosis of asthma.

- Table II summarises baseline data for the study population - you will see that 82% of patients had no asthma exacerbations in the previous year, 13% had just one asthma exacerbation, 4% had two asthma exacerbations and 2% had 3 or more asthma exacerbations. Of those who had one or more asthma exacerbations, about 70% had one exacerbation only (15,058/(15,058+4202+2138) - I think I said 90% in the meeting, so that was an overestimate).

- Table III summarises the number and % of the population who had different numbers of asthma exacerbations in the baseline and follow-up years.

- I recall there being a discussion about what proportion of exacerbations result in hospitalisation, and I think someone said about half. The data in this paper actually suggests that it is likely to be considerably less than that. Table II shows that only 0.6% of people had one or more asthma-related emergency department admissions. The paper does not report how many of these people were admitted to hospital as inpatients. However, even if all these people were admitted to hospital as inpatients (which is unlikely), that would still only mean that around 3% of people who had one or more exacerbations were hospitalised (696/(15,058+4,202+2,138).

McKeever et al. (2018) - I mentioned that around 50% of people with asthma who have had one or more exacerbations in the previous year will have another exacerbation in the following year. I got this estimate from the control group of this trial, which reported that 52% of participants in the control group had an asthma exacerbation in the year after randomisation. The target population for this trial was adults and adolescents who had had at least one exacerbation in the previous 12 months.

Whittaker et al. (2022) - this study also looked at routinely collected data from primary care records, but this time looked at rates of future exacerbations in people with COPD. The first paragraph of the results sections summarises numbers and % of patients who had different numbers of moderate and severe exacerbations. For context, the definition of exacerbations (asthma attacks) used in the study by Blakey et al. is consistent with severe exacerbations.

Appendix D3: Questions to Experts 19 September 2025

Expert contact details and declarations of interest:

Expert #1	[redacted]
Expert #2	[redacted]
Expert #3	[redacted]

General questions:

1. What proportion of patients undergo spirometry with bronchodilator reversibility (BDR) testing?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] I am not sure we can say what proportion of patients with suspected asthma or suspected COPD undergo spirometry BDR testing, as these terms are very subjective and not well coded in primary care electronic medical records, my experience is that the Read code for "suspected asthma" is used very infrequently. However, we have a better idea of what proportion of patients who receive a clinician diagnosis of asthma and COPD undergo testing. The national asthma and COPD audit programme Wales primary care audit 2021 reported that 43.9% of adults and 34% of children aged 6-18 years diagnosed with asthma during the last two years had a record of any objective measurement (includes spirometry, peak flow [>1 reading or evidence of peak flow diary] or FeNO – see page 11), and 1.9% of adults diagnosed with COPD during the last two years had received post-bronchodilator spirometry (page 9). The audit report can be accessed here: wales-primary-care_clinical-audit-report_2021_version-2-final_210722_0-2.pdf
Expert #3	[26/09/2025] Less than 50%

2. Would it be feasible to perform diagnostic spirometry with BDR testing at home?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] I would say that it is unlikely to be feasible to perform diagnostic spirometry with BDR testing at home, primarily because it is very difficult to do this to a high technical standard. I would say the main concern about administering the inhaler remotely is the patient having poor inhaler technique, resulting in the bronchodilator medication not reaching their lower airways. This could result in reversibility not being detected. From what I can understand, inhaler bronchodilators are safe for most patients to use.
Expert #3	[26/09/2025] No this is never done in practice.

Costs and modelling:

3. For standard care, we assumed across asthma (adults), asthma (children), and COPD populations that 63.2% will receive objective testing in 6 months using data from Howard et al. (2023). For the interventions, we have assumed two approaches:
    a. Higher proportions will receive objective testing within the same 6 month period (70%, 75%, 80% etc.)
    b. The same proportion will receive the testing but within a shorter time period (5 months, 4 months, 3 months etc.)

    Do these seem reasonable values to use in economic modelling?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] I am not sure I understand this question. Are you asking for a comparison in the proportions of asthma versus COPD populations who receive objective testing? What is the timing of the 3/4/5/6-month periods you are referring to? Are these the periods from the time of initial presentation with symptoms?
Expert #3	[26/09/2025] Yes

4. None of the companies have included costs for IT at each site to integrate the software. Would 3 hours Band 7 technologist be appropriate?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] No response

Expert #3	[26/09/2025] Probably more like 8 hours.

5. Due to the different technologies incurring different costs we are having to micro-cost spirometry.
    a. We are assuming practice nurse (Band 5 with additional qualifications) takes 30 minutes for measurement, and 10 minutes for interpretation in standard care. Does this seem appropriate?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] This sounds reasonable to me in terms of the time these activities might take. In reality, however, I very much doubt that a general practice would actually allocate this amount of time for a spirometry appointment. I would say 30 minutes at the most, but more likely 20 minutes of practice nurse time. Also, I would say that in most cases it is unlikely that the practice nurse will interpret the spirometry result unless they have had any specific training in how to do this (which is not the case in the majority of cases). It is more likely that they will do the test and the result will be scanned into the patient's electronic medical record for someone else e.g. a GP or another healthcare professional who has had specific training in spirometry interpretation to interpret and go through with the patient (e.g. respiratory specialist nurse, clinical pharmacist). I would say that the healthcare professional would be given about 10 minutes to explain the result to the patient and make a management plan.
Expert #3	[26/09/2025] Yes

    b. For the technologies in scope, we have assumed 20 minutes of a practice nurse (Band 5 but no additional qualifications) to support measurement, and additional 10 minutes of a practice nurse (Band 5 with additional qualifications) to support measurement and another 10 minutes for interpretation. Does this sound reasonable?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] No response
Expert #3	[26/09/2025] Realistically it is unlikely that two different members of staff will get involved in a single spirometry test. I would say 30 mins for measurement but remove the interpretation time since the AI will be doing this.

6. We are trying to apply a cost per patient to each technology. Some have an annual license/maintenance fee. We have currently assumed that this cost would be spread across 300 patients (which means that 300 patients would have the digital technology applied from a single practice in one year). This is based on an assumption from NG245.

    a. Is this volume representative of practice?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] I would say it is very difficult to make a “per practice” assumption like this, as there is so much variation (as you will see from the Asthma + Lung UK ICS review). However, if you need to make this type of assumption for your model then I would say it is reasonable to base your assumption on the one in NG245.
Expert #3	[26/09/2025] It would depend on the size of the practice but it sounds reasonable

    b. We can vary this within sensitivity analysis, is the range 100 to 1000 a valid range?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] Yes, I would say this is reasonable and that the extremes of your range most likely capture the likely variation.
Expert #3	[26/09/2025] Yes

7. Some technologies can be used at home. To consider the potential costs of this set up, we have assumed that 10% of users will require a mobile/tablet and a monthly mobile plan. Does this proportion seem appropriate?

Expert #1	[19/09/2025] I agree with this assumption, as I think 10% is a reasonable proportion to capture patients who may be harder to reach due to age, geography, disability, vulnerability, socioeconomic status,

	ethnicity, cultural factors, or lower levels of digital literacy, and to ensure they can receive equitable care and diagnosis.
Expert #2	[24/09/2025] No response
Expert #3	[26/09/2025] We have never needed to pay for a patient's monthly plan when using home spirometry

8. For the economic model, we need to pick a starting age of the cohort beginning the diagnostic pathway. There is limited evidence available. Can you please advise on the median age:

    a. Of adults starting diagnostic pathway for asthma – we have assumed 64 years

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] No, I would make the starting age younger e.g. 18 years.
Expert #3	[26/09/2025] This would be younger – say 30 years

    b. Of children starting diagnostic pathway for asthma – we have assumed 6 years

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] Yes, I think this is reasonable.
Expert #3	[26/09/2025] Yes

    c. Of adults starting diagnostic pathway for COPD – we have assumed 68 years

Expert #1	[19/09/2025] No response

Expert #2	[24/09/2025] I would be inclined to make it a bit younger e.g. 40 years (Prevalence of Chronic Obstructive Pulmonary Disease in England from 2000 to 2019 - PubMed)
Expert #3	[26/09/2025] Yes

9. For the economic model, we need to pick a proportion male of the cohort beginning the diagnostic pathway. There is limited evidence available. Can you please advise on the proportion male:

    a. Of adults starting diagnostic pathway for asthma – we have assumed 38%

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] I would say that is about right. The CPRD study by Blakey et al reported that 43% of patients with clinician diagnosed asthma in primary care are male: Identifying Risk of Future Asthma Attacks Using UK Medical Record Data: A Respiratory Effectiveness Group Initiative - PubMed
Expert #3	[26/09/2025] Yes

    b. Of children starting diagnostic pathway for asthma – we have assumed 38%

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] Yes, I would say this is reasonable. The Blakey paper I have linked to above included patients aged 12 years and above.
Expert #3	[26/09/2025] In children it is 50%. Asthma only has a female predominance in adults.

    c. Of adults starting diagnostic pathway for COPD – we have assumed 53%

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] Yes, I would say this is reasonable. This CPRD study reported that 53% with a COPD diagnosis in their primary care record were male (Table I - Frequency and Severity of Exacerbations of COPD Associated with Future Risk of Exacerbations and Mortality: A UK Routine Health Care Data Study - PubMed)
Expert #3	[26/09/2025] Yes

10. What proportion of patients at the start of the diagnostic pathway would be provided with treatment before the diagnostic objective testing has begun in the following cohorts:

    a. Adults with suspected asthma – 10%?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] I am not aware of any published evidence on this, but some colleagues who are doing a diagnostic test accuracy study in a CDC have told me that almost all patients referred to the CDC for investigation of suspected asthma have already been started on inhaled corticosteroids. So I would increase your estimate to at least 50%.
Expert #3	[26/09/2025] I suspect more like 25%

    b. Children with suspected asthma – 10%?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] I would say this is more reasonable, as people tend to be more reticent about starting children on inhaled corticosteroids empirically.
Expert #3	[26/09/2025] Again probably about 25%

c. Adults with COPD – 10%?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] Again, I am not aware of any published evidence on this and I have not done any work in patients with suspected COPD myself to be able to comment.
Expert #3	[26/09/2025] Yes

11. At the end of the diagnostic pathway (confirmed diagnosis) patients then enter a management pathway. We have identified a study by Lamber et al. which described even after diagnosis of COPD that 29.3% of patients receive medication at the end of the diagnosis phase, with the remaining being moved to an "uncontrolled" state.

    a. Is this approach appropriate for COPD?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] No response
Expert #3	[26/09/2025] This doesn't sound very realistic. If someone was diagnosed with COPD and was symptomatic I would expect their GP to treat them.

    b. Are we safe to assume that 100% of adults and children with asthma will receive medication within 1 year?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] I would be inclined to be a bit more conservative than assuming 100%. Although one would hope that people would receive treatment promptly after being given a diagnosis, things can slip through the net e.g. miscommunications resulting in medication not being prescribed, patients collecting prescriptions but not adhering to their medication regimen, patients not collecting prescriptions because

	they do not want to pay or cannot afford the prescription charge. Prescribing Patterns and Treatment Adherence in Patients with Asthma During the COVID-19 Pandemic - The Journal of Allergy and Clinical Immunology: In Practice reports that only 42% of people with asthma achieved "good adherence" to inhaled corticosteroid (ICS) treatment in 2020. If your definition of "receiving medication" means "being prescribed medication" I would say you can assume that the majority of people with asthma are prescribed medication within the first year of diagnosis e.g. 80%. However if your definition of "receiving medication" means "good adherence to prescribed medication regimen" then I reckon that figure is probably more like 40-50%.
Expert #3	[26/09/2025] Yes

12. With Markov economic modelling there is no patient history, therefore if a patient drops into an "exacerbation" state, we don't know their previous level of control. We have therefore assumed that 23% go back to "controlled", 30% to "partially controlled" and 48% "uncontrolled" using data from Furhan et al. 2011 (study in children).

    a. Do these values seem reasonable?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] The study by Fuhrman et al. 2011 which you have cited was conducted in children who had been hospitalised for an asthma exacerbation. As I mentioned in my email to Ros Parker on 16th September 2025, only a very small proportion of people who have one or more asthma exacerbations in a 12-month period are hospitalised (I estimated in my email to Ros up to 3%). So I feel you should reconsider these values in the context of all exacerbations, including those which are managed in the community, not just those which result in hospitalisation (see comments below for point b).
Expert #3	[26/09/2025] Yes

    b. Could we broadly apply these to asthma (adults) and COPD?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] Table III in the study by Blakey et al (which I sent to Ros Parker on 16th September 2025, Identifying Risk of Future Asthma Attacks Using UK Medical Record Data: A Respiratory Effectiveness Group Initiative - PubMed) shows that in a primary care asthma population aged 12-80 years, 15-18% have one or more asthma exacerbations and around 5% have two or more asthma exacerbations in a 12-month period. Based on this you could say that around 30% of people who have an asthma exacerbation in a given 12-month period will have at least one more exacerbation in that same 12-month period (5%/15-18%). So I would say that after an exacerbation it would be reasonable to say around 30% of patients remain uncontrolled. I am not sure there are sufficient data to underpin robust estimates of how many patients go to "partially controlled" or "controlled" after an exacerbation. However, one way to approach this might be to estimate the proportion who go back to "controlled" based on the proportion who achieve good medical adherence. In this paper Prescribing Patterns and Treatment Adherence in Patients with Asthma During the COVID-19 Pandemic - The Journal of Allergy and Clinical Immunology: In Practice it was estimated that about 42% of people with asthma (whether or not they have had a previous exacerbation in the last year) achieve good adherence to inhaled corticosteroids (take 75% or more of what they are prescribed). The figure in people who have had one or more exacerbations in the last year is likely to be lower, as poor adherence is a well recognised driver of asthma exacerbations. If 42% of the remaining 70% of patients become controlled as a result of good medication adherence, this means about 30% of people who have had an exacerbation go back to being controlled (42% of 70% = 29.4%). So in summary, you could estimate that after an asthma exacerbation, 30% go back to being controlled, 40% go back to being partially controlled and 30% remain uncontrolled. I'm afraid I cannot comment on COPD as I am less familiar with that literature.
Expert #3	[26/09/2025] Yes

13. We have also included additional health states to account for a proportion of patients who have a diagnosis of asthma, however on monitoring over time may have this diagnosis removed (that is the original diagnosis was incorrect).

a. Some literature suggests that this proportion may be 30%. Is that proportion plausible and reflective of your experience in adults? And children?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] I would say that is reasonable to assume that around 30% of asthma diagnosis in adults are incorrect. This study by Aaron and colleagues found that among adults with physician-diagnosed asthma 33% had no objective evidence of asthma based on spirometry or bronchial challenge testing: Reevaluation of Diagnosis in Adults With Physician-Diagnosed Asthma - PubMed. However, this may not necessarily result in the asthma label being removed. Firstly, many incorrect diagnoses may not be picked up in routine clinical care as people may not undergo repeat testing either because the clinician is not aware that this is needed or because of lack of access to tests (or both). Also, once someone has been given a "label" of asthma it is very difficult to remove that label. Patients become very attached to the label and worry that they will come to harm if it is removed and their medication is stopped. A colleague of mine who works in secondary care gets around this by telling people they have "low risk asthma" or "burnt out asthma" and often allows them on continue on ICS-LABA on an AIR regimen so that they do not feel that their medication has been taken away altogether and they have the "safety net" of having something to take if their symptoms do get worse again. I cannot comment on whether the same dynamic applies in children. However, the literature suggests that overdiagnosis of asthma in children is also common: Overdiagnosis of asthma in children in primary care: a retrospective analysis - PubMed. This study reports that only 16.1% of children with a clinician diagnosis of asthma had this diagnosis confirmed with spirometry.
Expert #3	[26/09/2025] I suspect that the diagnosis of asthma is removed less commonly than this, perhaps 10% of the time.

b. Can you please help describe the health impact of an incorrect asthma diagnosis (providing inhaled steroids) on an adult or child?

Expert #1	[19/09/2025] No response

Expert #2	[24/09/2025] I would say the health impact is two-fold. One aspect is, as you say, the consequences of giving people medication e.g. inhaled corticosteroids which they do not need. This can result in steroid-related adverse consequences as you have mentioned in point c. However, those sorts of consequences tend to be associated with prolonged use of high dose inhaled corticosteroids or oral corticosteroids which is relatively uncommon in primary care asthma populations. I would say that the more relevant aspect in primary care is that the patient does not get the treatment they actually need because the correct underlying cause has not been identified. The health impact of this depends on what the correct underlying cause is, how severe the condition actually causing the symptoms is, and how far/how quickly the condition progresses in the absence of the correct treatment/management. If the underlying cause is something which is relatively mild (e.g. mild allergic rhinitis) then the impact may be relatively small e.g. impaired quality of life, possibly some time off work/leisure activities. However, if a serious underlying pathology is missed (e.g. lung cancer, ischaemic heart disease) then the impact of that is potentially much more serious particularly if the diagnosis is made late or not at all. This paper describes co-morbidities found in people with asthma in primary care: Comorbidities in adults with asthma: Population-based cross-sectional analysis of 1.4 million adults in Scotland - PubMed.
Expert #3	[26/09/2025] Inhaled steroids don't have much in the way of side-effects but they can cause oral thrush, as well as being an unnecessary cost and inconvenience for the patient.

c. We have assumed misdiagnosis of asthma may delay alternative diagnosis, and long-term use of inhaled steroids may impact bone, muscle, psychiatric, cardiovascular, ocular, and metabolic disease (Kavanagh et al. 2019) may also impact quality of life. Therefore, are we correct to assume that a utility decrement for those misdiagnosed?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] Yes, that sounds reasonable to me.
Expert #3	[26/09/2025] Yes

d. Is it plausible that use of the technologies listed in the scope may identify these misdiagnoses earlier than standard care?

Expert #1	[19/09/2025] No response
Expert #2	[24/09/2025] No response
Expert #3	[26/09/2025] Yes

Thank you very much for your time and expertise.

Appendix D4: Data from SPIRO-AID Trial

Please can you help complete the following tables (where the pulmonary experts were stated as the reference standard).

Population: Asthma

Comparator: standard care

-	Test +ve	Test -ve	Total
Disease	Total Responses with asthma where cases are actual asthma [redacted]	Total Responses with anything other than asthma where cases are actual asthma [redacted]	All asthma traces x number of participants [redacted]
No Disease	Total Responses with asthma where cases are not asthma [redacted]	Total Responses with anything other than asthma where cases are not asthma [redacted]	All non-asthma cases x number of participants [redacted]
Total	Total Asthma responses [redacted]	Total non-asthma responses [redacted]	[redacted]umber of participants x 50 [redacted]

EAG calculated results: Sensitivity: [redacted] Specificity: [redacted]

Intervention: standard care plus ArtiQ.Spiro

-	Test +ve	Test -ve	Total
Disease	Total Responses with asthma where cases are actual asthma [redacted]	Total Responses with anything other than asthma where cases are actual asthma [redacted]	All asthma traces x number of participants [redacted]
No Disease	Total Responses with asthma where cases are not asthma [redacted]	Total Responses with anything other than asthma where cases are not asthma [redacted]	[redacted]ll non-asthma cases x number of participants [redacted]
Total	Total Asthma responses [redacted]	Total non-asthma responses [redacted]	[redacted]umber of participants x 50 [redacted]

EAG calculated results: Sensitivity: [redacted] Specificity: [redacted]

Population: COPD

Comparator: standard care

	Test +ve	Test -ve	Total
Disease	Total Responses with COPD where cases are actual COPD [redacted]	Total Responses with anything other than COPD where cases are actual COPD [redacted]	All COPD traces x number of participants [redacted]
No Disease	Total Responses with COPD where cases are not COPD [redacted]	Total Responses with anything other than COPD where cases are not COPD [redacted]	All non-COPD cases x number of participants [redacted]
Total	Total COPD responses [redacted]	[redacted]otal non-COPD responses [redacted]	[redacted]umber of participants x 50 [redacted]

EAG calculated results: Sensitivity: [redacted] Specificity: [redacted]

Intervention: standard care plus ArtiQ.Spiro

-	Test +ve	Test -ve	Total
Disease	Total Responses with COPD where cases are actual COPD [redacted]	[redacted]otal Responses with anything other than COPD where cases are actual COPD [redacted]	All COPD traces x number of participants [redacted]
No Disease	Total Responses with COPD where cases are not COPD [redacted]	Total Responses with anything other than COPD where cases are not asthma [redacted]	[redacted]ll non-COPD cases x number of participants [redacted]
Total	Total COPD responses [redacted]	[redacted]otal non-COPD responses [redacted]	[redacted]umber of participants x 50 [redacted]

EAG calculated results: Sensitivity: [redacted] Specificity: [redacted]

NICE Health Tech Programme

GID-HTE10065 Algorithms applied to spirometry to support the diagnosis of lung conditions in primary care and community diagnostic centres

External Assessment Report (EAR) and economic model

Collated comments table

Any confidential sections of the information provided should be underlined and highlighted. Please underline all confidential information, and separately highlight information that is 'commercial in confidence' in blue and all that is 'academic in confidence' in yellow

Redacted External Assessment Report – Collated comments table:

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
1	ArtiQ, a Clario company	109	6.2.4	ArtiQ.Spiro integration cost is set to £2.38/patient (Table 27). However, as documented in Appendix C2, no integration cost is charged. There is also no integration cost expected as the users already have their spirometer installed and no additional software installation or integration is needed. The user only needs to enter a username and keycode, provided by ArtiQ. We request that this integration cost is removed.	Thank you for your comment. The EAG have added to section 6.2.4 to highlight this stakeholder consultation comment but would consider £0 integration costs for implementing a new technology in the NHS as unlikely. Taking a cautious and consistent approach the EAG have maintained adding £2.38 to the costs of ArtiQ.Spiro, noting that this additional cost may include additional implementation costs such as IT, setting up usernames, and training. The EAG have further highlighted in the adult asthma results that applying the costs of ArtiQ.Spiro resulted in the intervention being dominant, and that removing £2.38 would increase the incremental cost savings associated and that

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
					the intervention remained dominant. Therefore, the impact of this is small.
2	ArtiQ, a Clario company	120	6.3.1.2	Faster access to objective testing is seen as an “implausible scenario” based on reduction of interpretation time. However, if technologies, such as ArtiQ.Spiro, allow workforce upskilling this can increase workforce capacity and therefore faster access to objective testing. An example of this approach is shown in the publication of Hayes et al. 2025, showing that this scenario is not implausible.	Thank you for your comment. The EAG has acknowledged this as another potential way to achieve faster access to spirometry testing and removed the wording “implausible”. The EAG consider that a reduction in interpretation time (from 10 minutes) may not significantly increase the overall testing capacity. The EAG used the mean reduction in interpretation time to 5 minutes (reported by Adams 2025) in the base case, however the impact of this on overall test capacity remains unclear. The EAG note that Hayes et al. (2025b) (referenced within this comment) used band 3 Respiratory Care and Support Workers (unregistered with Association for Respiratory Technology and Physiology (ARTP) supported by band 6 or 7 ARTP certified nurses (who conducted spirometry interpreting). The EAG note, as per the NICE Final Scope, there is national recognition that staff performing or interpreting spirometry should be certified and registered with the ARTP. The EAG have used the cost of a band 5 practice nurse with qualifications (to represent ARTP training) to conduct and interpret spirometry test in line with these current recommendations. The EAG note that the comparator (standard care) assumed 30 minutes measurement and 10 minutes interpretation by a Band 5

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
					practice nurse with qualifications (staff time cost £35.33). The intervention (for all technologies expect NuvoAir) assumed 25 minutes measurement and 5 minutes interpretation by a Band 5 practice nurse with qualifications (staff time cost £26.50). If the staffing band was changed to 25 minutes measurement with a Band 4 nurse with qualifications, followed by 5 minutes with a Band 6 nurse with qualifications this staff time cost would reduce to £24.08. Applying these changes to staff bands for ArtiQ.Spiro, would still result in ArtiQ.Spiro being dominant.
3	ArtiQ, a Clario company	127	6.3.2	Please note that ArtiQ.Spiro does not provide disease suggestions for underage patients. It does provide physiological interpretation and quality feedback.	Thank you for clarifying – this has been added to Section 2: Technologies.
4	Association of Respiratory Nurses (ARNS)	29	2	It is vital that the patient's clinical history is taken in context of the full diagnostic picture as objective testing remains a tool to **support** and **aid** diagnosis, but not to make the diagnosis. Caution must be taken in technologies which do not include a clinical history in the algorithms to aid the user (clinician interpreting results), and it would be advisable that a clinician who is highly skilled in diagnostics, has relevant accreditation e.g. ARTP to use and interpret the results from technologies **which do not include clinical history taking** in their algorithms.	Thank you for this valuable insight – this has been noted in the EAG report.
5	Association of Respiratory Nurses (ARNS)	29	2	LungHealth does not interpret the equality of spirometry tests from patient effort, using flow volume/volume-time loops. Only data is inputted i.e. numbers. Again, it would be reliant on the healthcare professional to be able to interpret the quality of the spirometry test, to determine if it is repeatable/reproducible to be able to interpret accurately in a clinical context. Potentially adds increased workload to the interpreter to ensure the results inputted are reliable to use.	Thank you – this has been noted in the EAG report.

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
6	Association of Respiratory Nurses (ARNS)	29	2	Nuvoair is used for monitoring respiratory disease, not full spirometry testing. Spirometry for non-diagnostic purposes is less common in Primary care and community settings so unsure of the value of the technology in this setting. May be helpful for Secondary care and disease monitoring.	Thank you for your comment – the EAG recognises how NuvoAir is currently used. However, because it could be used for diagnosis and was listed in the scope, it has been included in the assessment. The EAG have added to Section 2 the potential value of using NuvoAir in secondary care and in monitoring disease but have clarified that these potential uses are out of scope of this early value assessment.
7	Association of Respiratory Nurses (ARNS)	32	3.2	There is data on the number of currently registered ARTP accredited professionals by region here: Spirometry Register | ARTP Spirometry	This is very helpful, thank you. We have added the link and number of current active registrants by home nation have been added to Section 3.2.
8	Association of Respiratory Nurses (ARNS)	89	6.2	The model itself was coded in R Programming Language, using the **'rdecision'** package – typo 'decision'	Thank you for your comment – the package used was 'rdecision' (details available here), so no change needed.
9	Association of Respiratory Nurses (ARNS)	141	8	Table 37 - AI in **PRImary** Care Spirometry Pathways for Diagnosis of Lung Disease – typo "Primary"	Thank you for your comment – the name of the study has been reported correctly, as shown on the NCT record here.
10	Association of Respiratory Nurses (ARNS)	N/A	N/A	Consider separating technologies' guidance as they differ widely. Consider the "readiness" of each technology in a real-world clinical setting. ArtiQ.Spiro seems to be closest to near-term evaluation for adoption, while others remain in pre-adoption or evidence-generation phases.	Thank you for your comment. The EAG have summarised that the evidence is most comprehensive for ArtiQ.Spiro (Executive Summary) and listed the evidence gaps for the other technologies (in Section 8.2) EAG note that technology-based recommendations will be considered by Committee in preparation of the Draft Guidance.
11	Association of Respiratory Nurses (ARNS)	N/A	N/A	There is a need to improve data collection from spirometry referrals at CDC / PCN level. Consider a recommendation of pilot sites for new technologies (which require more real-world, comparative) in established CDCs in underserved / digitally constrained settings.	Thank you for your comment. The EAG have stated that the number of referrals to secondary care as outcomes of interest in their evidence generation recommendations (Table 39, #2). The EAG note that this will be

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
					considered by Committee in preparation of the Draft Guidance.

Redacted Economic Model – Collated comments table:

Comment no.	Stakeholder	Page no.	Section no.	Comment	EAG Response
1	Association of Respiratory Nurses (ARNS)			No comments from ARNS regarding economic model documents	Thank you for your comment.

NICE National Institute for Health and Care Excellence

Medical Technologies Advisory Committee Interests Register

Topic: HTE10065 Algorithms applied to spirometry to support the diagnosis of lung conditions in primary care and community diagnostic centres

NICE's declaration of interest policy can be accessed here

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
John Cairns	Standing Committee Member	Financial Interests	Advising Pierre Fabre on oncology submission	May 2024	16 June 2025	June 2024	Declare and participate
			Advising Janssen UK on metastatic urothelial carcinoma	May 2024	16 June 2025	June 2024	Declare and participate
			Advice to Johnson & Johnson on economic modelling of a treatment for non-small-cell lung cancer.	July 2024	16 June 2025 / 2 July 2025	August 2024	Declare and participate
			Advising Pierre Fabre on economic modelling of a treatment for non-small-cell lung cancer.	August 2024	16 June 2025	October 2024	Declare and participate
			Advising Johnson & Johnson Innovative on economic modelling of a treatment for multiple myeloma.	May 2025	16 June 2025 / 2 July 2025	May 2025	Declare and participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			Advice to BeiGene on economic modelling of a treatment for small cell lung cancer.	October 2024	16 June 2025 / 2 July 2025	ongoing	Declare and participate
		Non-financial professional and personal interests	None	n/a	16 June 2025	n/a	No further action
		Indirect interests	None	n/a	16 June 2025	n/a	No further action
Joy Allen	Standing Committee Member	Financial Interests [VO1]	Employee of Roche Diagnostics Ltd since August 2021 who manufacture NTproBNP and multiple respiratory diagnostic tests.	31/08/2021	23 June 2025 / Nov 2025	Present	Declare and participate
			My employer, Roche Diagnostics Ltd. have a molecular portfolio for respiratory ID (for lab and point of care) and a histopathology portfolio for lung cancer. I can provide more details if needed. ** ID (Infectious Diseases)*	31/08/2021	23 June 2025	Present	Declare and participate
		Non-financial professional and personal interests	None	n/a	23 June 2025	n/a	No further action
		Indirect interests	None	n/a	23 June 2025	n/a	No further action
Patrick McGinley		Financial Interests	I prove ad hoc advice on financial flows to MTechAccess on a paid basis. The work involved covers none of the technologies or companies involved in this evaluation.	January 2020	Nov 2025	ongoing	Declare and participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
	Standing Committee Member		I'm Hon Treasurer to Association for Study of Obesity.	January 2020	Nov 2025	ongoing	Declare and participate
		Non-financial professional and personal interests	None	n/a	Nov 2025	n/a	No further action
		Indirect interests	None	n/a	Nov 2025	n/a	No further action
Keith Abrams	Standing Committee Member	Financial Interests	Alongside my academic roles, I have provided advice and undertaken analysis for a number of pharmaceutical and biotech companies related to HTA activities and am listed as a director of Visible Analytics Limited, a company providing HTA services. I have not provided consultancy to any of the stakeholders listed for these appraisals.	2019	Nov 2025	Ongoing	Declare and participate
		Non-financial professional and personal interests	None	n/a	Nov 2025	n/a	No further action
		Indirect interests	None	n/a	Nov 2025	n/a	No further action
Gillian Doe	Professional Expert	Financial Interests	Employed by University of Leicester as research programme manager for National Institute for Health Research (NIHR) project through an AI Award in Health and Care (Phase 3- Application: Grant number AI_AWARD02204). Evaluation of ArtiQ.Spiro, an AI decision support software, in primary care spirometry pathways.	March 2022	24 June 2025	Sep 2025	Attending as expert – no further action
			Early career researcher award from ALUK (£89k) to explore help seeking for breathlessness in diverse communities.	October 2024	24 June 2025	July 2026	Attending as expert – no further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			Innovate UK Accelerate Knowledge Transfer 2 Innovate (AKT2I) award (£39k) to digitally optimise the clinical Breathlessness service in Leicester – proof of concept.	Jan 2024	24 June 2025	June 2024	Attending as expert – no further action
		Non-financial professional and personal interests	International Primary Care Respiratory Group Breathlessness working group	2023	24 June 2025	Ongoing	Attending as expert – no further action
			First author and co-author on following publications: DOI: 10.1136/bmjopen-2024-086736 DOI: 10.1183/23120541.00116-2025 DOI: 10.3399/BJGP.2022.0608	2022	24 June 2025	Ongoing	Attending as expert – no further action
			Accepted for publication in NEJM AI: SPIRO-AID: A Randomized Controlled Trial of AI-Assisted Spirometry Interpretation in Primary Care		24 June 2025		Attending as expert – no further action
			Research programme manager for National Institute for Health Research (NIHR) project through an AI Award in Health and Care (Phase 3-Application: Grant number AI_AWARD02204). Evaluation of ArtiQ.Spiro, an AI decision support software, in primary care spirometry pathways.	March 2022	24 June 2025	Sep 2025	Attending as expert – no further action
		Indirect interests	Associate Editor Nature Partner Journal: Primary Care Respiratory Medicine	Jan	24 June 2025	2025	Attending as expert – no further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
William Man	Professional Expert	Financial Interests	Private practice – I am a full-time NHS consultant. I also provide private medical services outside my NHS work. I request lung function tests as part of these medical services. Since 2023, I receive modest reimbursement to report the lung function tests for my patients from the hospitals performing the lung function tests. I do not utilise any artificial intelligence software to interpret lung function tests or produce interpretation reports.	2009	18 June 2025	Ongoing	Attending as expert – no further action
		Non-financial professional and personal interests	Honorary President of the Association for Respiratory Technology and Physiology (ARTP). This is a non-reimbursed role. The ARTP are the professional guardians of physiological measurement and interpretation within the field of respiratory medicine for the United Kingdom.	2022	18 June 2025	Ongoing	P Attending as expert – no further action
			I am the Chief Investigator for a National Institute for Health Research Artificial Intelligence Award that funded a series of studies intended to validate a spirometry interpretation software produced by ArtiQ.Eu (now part of the Clario group). I am an author of several publications that have arisen from this award. I am not currently aware as to whether any of these will be submitted as evidence publications to the NICE advisor committee. I received no financial imbursement from the commercial company.	2022	18 June 2025	30 March 2025	Attending as expert – no further action
		Indirect interests	None	n/a	18 June 2025	n/a	No further action
Miss Laura Graham	Professional Expert	Financial Interests	None	n/a	23 July 2025	n/a	No further action
		Non-financial professional and personal interests	Co-Chair London Clinical Networks Pulmonary Rehabilitation Group	February 2019	23 July 2025	-	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
		Non-financial professional and personal interests	Member of the London Clinical Respiratory Network Leadership Group	February 2019	23 July 2025	-	No further action
		Non-financial professional and personal interests	British Thoracic Society – Specialist Advisory Group Pulmonary Rehabilitation	February 2019	23 July 2025	December 2022	No further action
		Indirect interests	None	n/a	23 July 2025	n/a	No further action
Dr Sherif Gonem	Specialist Committee Member	Financial Interests	None	n/a	2 July 2025 & 20 August 2025	n/a	No further action
		Non-financial professional and personal interests	I have written an editorial commenting on a paper/research study which tests an AI technology for interpreting lung function tests. The editorial has now been published in ERJ Open Research: https://publications.ersnet.org/content/erjor/11/5/00353-2025 It is fairly neutral in tone and does not express a strong view in favour of or against the technology in question.	8 April 2025	2 July 2025 & 20 August 2025 & 3 Nov 2025 (at publication)	Ongoing – article now published [VO1]	Declare and participate
			I am a co-author on a paper testing an AI technology for interpreting lung function tests (Eur Respir J. 2023 May 18;61(5):2201720). I was not one of the lead investigators. The paper was published more than 12 months ago. Co-author on a publication which may be relevant to the topic: "Collaboration between explainable artificial intelligence and	18 May 2023	2 July 2025 & 20 August 2025	-	Declare and participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			pulmonologists improves the accuracy of pulmonary function test interpretation. Eur Respir J. 2023 May 18; 61(5): 2201720.)				
			I wrote a letter commenting on a paper which tested an AI technology for interpreting lung function tests (Eur Respir J. 2019 Jun 5;53(6):1900638). This was published more than 12 months ago.	June 2019	2 July 2025	-	Declare and participate
		Indirect interests	None	n/a	2 July 2025& 20 August 2025	n/a	No further action
Dr Peter Saunders	Specialist Committee Member	Financial Interests	Advisory board fees, Trevi Therapeutics (Currently developing a drug for the treatment of pulmonary fibrosis related cough)	2022	14 July 2025	Ongoing occasional commitment	Declare and participate
		Non-financial professional and personal interests	Ongoing involvement in multiple clinical trials (phase II and III) for the development of new therapeutics to treat interstitial lung disease	2022	14 July 2025	Ongoing	Declare and participate
			Local PI in a clinical trial evaluating the use of home spirometry devices in the management of progressive lung fibrosis (I-FILE study, Erasmus University Netherlands) (Site principle investigator for the I-FILE study (Sponsor -Erasmus University) – A study of home spirometry in patients with progressive pulmonary fibrosis)	2022 Nov 2022	14 July 2025 9 Nov 2025	Ongoing Ongoing	Declare and participate
		Indirect interests	None	n/a	14 July 2025	n/a	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Miss Laura Beattie	Lay Specialist Committee Member	Financial Interests	I am involved in the CF Trust and LifeArc Innovation Hub in which I am paid for this role to be a patient advisor and member of the hub (I am not employed)	September 2023	18 June 2025 & 15 September 2025	Ongoing	Declare and participate
			Lay Member on the NICE Indicator Advisory Committee	July 2025	18 June 2025 & 15 September 2025	Ongoing	Declare and participate
		Non-financial professional and personal interests	Member of the CF Trust Quality Improvement Group - Volunteer role	September 2021	18 June 2025 & 15 September 2025	Ongoing	Declare and participate
			Member of the CF Trust Involvement Group which is a focus groups to discuss specific projects within the Trust or projects that research teams are developing - Volunteer role	September 2024	18 June 2025 & 15 September 2025	Ongoing	Declare and participate
			I use Nuvo Air with my Cystic Fibrosis. I also am part of Pulse-CF looking into CF Infections which requires home monitoring (https://www.pulse-cf.com/)	Ongoing	28 October 2025	Ongoing	Declare and participate
		Indirect interests	My Dad works for the NHS Mental Health Service as an IT Engineer	January 2011	18 June 2025 & 15 September 2025	Ongoing	No further action
			My Mum works for Manchester City Council for Children's Services	September 2010	18 June 2025 & 15 September 2025	Ongoing	No further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
Mrs Terri-Lynn Quigley	Lay Specialist Committee Member	Financial Interests	None	n/a	10 July 2025	n/a	No further action
			I work for Cheshire & Merseyside ICB on the CYP Transformation Programme, specifically on asthma	7/11/23	5 Nov 2025	Date	Declare and participate
		Non-financial professional and personal interests	None	n/a	10 July 2025	n/a	No further action
		Indirect interests	None	n/a	10 July 2025	n/a	No further action
Dr Enya Danes	Specialist Committee Member	Financial Interests	Chiesi Chiesi – consultancy fee for COPD outreach events (non-diagnostic)	03/10/2024 May 2024	10 July 2025 21 August 2025	05/10/2024 October 2024	Declare and participate Declare and participate
			Fisher and Paykel I was invited to do a talk for a conference (the CARE convention) and the speaker fee was funded by Fisher and Paykel. It wasn't related to any products directly.	01/07/2024	10 July 2025	30/07/2024	Declare and participate
			The Royal College of Physicians	01/02/2024	10 July 2025	-	Declare and participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			Royal college of physicians paid employment (2hrs per week) Quality Lead for Pulmonary Rehabilitation Services Accreditation Scheme	February 2024	21 August 2025	Present	Declare and participate
		Non-financial professional and personal interests	None	n/a	10 July 2025 & 21 August 2025	n/a	No further action
		Indirect interests	None	n/a	10 July 2025 & 21 August 2025	n/a	No further action
Dr Karl Sylvester	Professional Expert	Financial Interests	Medical Advisory Board Member – ndd Technologies – providing consulting advice on strategic development of respiratory physiological diagnostic devices incorporating automated interpretation The board meets virtually every 2 months to discuss the future direction of devices and software. We have a 3 day face to face meeting going further into depth on our opinions on where the company should take their products based on our current knowledge of the testing environment. We conduct research on behalf of the company that supports their future strategy and provides ongoing solutions to problems they face in device delivery.	September 2023	7 July 2025 & 21 August 2025	Ongoing	Attending as expert – no further action
			Co-investigator on a number of trials utilizing ARTIQ spirometry interpretation software to support diagnosis of respiratory disease in the community I have received a financial contribution for my time in analysing spirometry traces to determine their quality and diagnostic accuracy. My output was	January 2022	21 August 2025	July 2025	Attending as expert – no further action

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			then compared to the ARTIQ software to determine where interpretative differences may lay. This was a grant funded study via the Royal Brompton & Harefield hospital, but with direct input from the ARTIQ team.				
		Non-financial professional and personal interests	Development of AI CPET interpretation – UCLA Stakeholder/Advisor in the development of UCLA Cardiopulmonary exercise testing AI interpretation software. Supported initial trial of application in comparison to usual manual interpretation methods Does not include work with any of the listed manufacturers/technologies	April 2025	7 July 2025 & 21 August 2025	Ongoing	No further action
			Development of AI CPET interpretation - KU Leuven Does not include work with any of the listed technologies/manufacturers	Yet to start	7 July 2025	-	No further action
			Stakeholder/Advisor in the development of University of Leuven, Belgium Cardiopulmonary exercise testing AI interpretation software. Co-investigator in a prospective multi-center trial Does not include work with any of the listed technologies/manufacturers	September 2025	21 August 2025	-	No further action
		Indirect interests	None	n/a	7 July 2025 & 21 August 2025	n/a	No further action
Mrs Cheryl O'Sullivan	Specialist Committee Member	Financial Interests	None	n/a	17 Sep 2025	n/a	No further action
			Paid employment as Advanced Nurse Practitioner in Long Term Conditions at South Coast Medical Group PCN	2014	30 October 2025	Ongoing	Declare and participate

Name	Role with NICE	Type of interest	Description of interest	Interest arose	Interest declared	Interest ceased	Comments
			Paid employment as Chief Nursing Information Officer and Clinical Safety Officer at NHS Dorset	2022	30 October 2025	Ongoing	Declare and participate
		Non-financial professional and personal interests	None	n/a	17 Sep 2025	n/a	No further action
		Indirect interests	None	n/a	17 Sep 2025	n/a	No further action
Dr Rosemary Marsh	Specialist Committee Member	Financial Interests	GP partner	01/04/2023	24 Sep 2025	Ongoing	Declare and participate
			ICB clinical lead, NCL ICB	01/04/2023	24 Sep 2025	Ongoing	Declare and participate
		Non-financial professional and personal interests	None	n/a	24 Sep 2025	n/a	No further action
		Indirect interests	None	n/a	24 Sep 2025	n/a	No further action