

Rethinking respiratory disease diagnosis: insights from an evolving technology landscape

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Short Report

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Abstract

Chronic respiratory diseases (CRDs) represent a major global health burden, with diagnosis frequently delayed by overlapping symptoms, limited access to testing and reliance on effort-dependent lung function measures. Earlier diagnosis in primary care remains a critical unmet need.

We reviewed the current and emerging landscape of CRD diagnostics using a market intelligence database (GlobalData), focusing on technologies with potential to support early diagnosis and triage.

The current diagnostic landscape is dominated by lung function testing, particularly spirometry. However, the development pipeline suggests a shift towards indirect approaches, including breath analysis and acoustic technologies. These emerging technologies offer the potential for more accessible, patient-centred diagnostics suited to primary care and other community settings. However, realising this potential will require robust validation and integration within clinical pathways. In addition, innovation remains concentrated on more prevalent CRDs with comparatively limited activity focused on rarer conditions.

Addressing this imbalance will be critical to improving equity and reducing diagnostic delay for all individuals living with CRD. Co-ordinated action from innovators, funders and system decision-makers will be essential to accelerate the translation of the most promising solutions into clinical practice, while ensuring that the needs of those with rarer lung conditions are not overlooked.

Introduction

Chronic respiratory diseases (CRD) are a significant yet often neglected health burden, which collectively contribute to 7% of all-cause mortalities worldwide[1]. In the UK, CRD represents the third leading cause of death by disease[2] costing an estimated £188 billion annually, including £10 billion in direct costs to the UK National Health Service[3].

Early diagnosis and intervention could improve patient outcomes by helping to slow or stop disease progression and prevent irreversible lung damage caused by attacks and exacerbations[4, 5]. However, early detection and diagnosis remains a major global challenge[6, 7], with patients often waiting years for a diagnosis[8]. The journey to diagnosis is complicated by a number of factors including the overlapping symptoms for different CRDs, which can increase the risk of misdiagnosis[9], and a lack of accessible and accurate tests.

Efforts to improve respiratory diagnostics have highlighted a critical need for tools that are accessible, accurate and suitable for use in primary care, where most patients first present[10, 11]. Existing approaches often rely on effort-dependent testing and may not perform well in early disease or in the context of multimorbidity. This has driven increasing interest in alternative diagnostic approaches that are less burdensome for patients and more feasible within routine care pathways. Against this backdrop,

understanding the current and emerging diagnostic landscape is essential to identify opportunities for innovation and to guide the development of tests that meet both patient and system needs.

To characterise the landscape of diagnostic tools that could address the unmet need, we conducted a review of tests for CRD that are either regulatory approved or in development using the GlobalData Medical Intelligence Center database. This included technologies that have obtained regulatory approval but are not yet widely implemented in clinical practice, as well as emerging tests with potential applicability in primary care to support CRD diagnosis. The review focused on four common CRDs; asthma, bronchiectasis, chronic obstructive pulmonary disease (COPD), and interstitial lung disease (ILD), selected for their prevalence, overlapping symptoms, and shared diagnostic challenges[9, 12].

Methods

Diagnostic technologies were identified using the GlobalData Medical Devices Intelligence Center database (<https://www.globaldata.com>), see supplemental methods. Products were included if they were either approved or in development and relevant to the diagnosis or monitoring of asthma, COPD, bronchiectasis or interstitial lung disease (Table S1). Technologies were categorised by modality and intended use, and descriptive analyses were conducted to characterise the current landscape and development pipeline.

Acoustics and breath analysis products were further examined using a strengths, weaknesses, opportunities and threats (SWOT) framework. These technology classes showed substantial activity across the development pipeline, including clinical and preclinical stages, and in the published literature. They also have attributes that may support translation into primary care settings.

Results

Diagnostic tests with regulatory approval

To identify tests with potential utility to diagnose CRD in a primary care setting, we searched for all tests in GlobalData that were intended for the diagnosis or monitoring of asthma, bronchiectasis, COPD, or ILD. The search identified 137 approved tests (see Table S2 for the full list) grouped into 8 categories (Fig. 1, Table 1).

The current diagnostic landscape remains heavily reliant on lung function testing, particularly spirometry, which accounts for a substantial proportion of approved technologies (47/137). While well established in clinical practice, spirometry has several limitations impacting its use in primary care as a diagnostic for CRDs. These include low sensitivity to the early signs of disease[13], a requirement for appropriately trained staff[14–16], and variable access and availability in primary care[17]. Furthermore, successful testing depends heavily on patient effort and their understanding of instructions[16, 18]. Around one in six patients report finding the test difficult, with common challenges including coughing, fatigue, breathlessness, and sustaining a prolonged forced exhalation[18].

There were alternative approved tests which measure lung function, such as oscillometers (Table 1). Oscillometry may help to diagnose COPD, asthma and ILD[19, 20] by measuring rhythmic changes during tidal breathing and offers an alternative to the forced exhalation used by spirometry. This test is considered quick and low effort for patients to perform, but the interpretation requires specialist knowledge which has limited its use[21]. Advances in AI may help overcome this barrier and make it more suitable for a primary care environment.

Most approved tests are indicated for the diagnosis or monitoring of asthma (51) and COPD (33), or both conditions (40) (Fig. 1B). This is in line with asthma and COPD being the most prevalent CRDs [1, 6] and therefore representing the largest CRD testing market. A lack of suitable tools to detect rarer conditions, such as bronchiectasis and ILD, can increase the diagnostic timelines for these patients and lead to poorer outcomes[8, 22–24].

Diagnostic tests within the development pipeline

Within the USA and Europe developmental pipeline, 47 tests were within scope to provide a diagnosis of asthma, bronchiectasis, COPD, and/or ILD, based on the test’s description (Fig. 1, Table 1). An additional 22 tests were identified as tools intended for monitoring (Fig. 1, Table 1); although most are currently positioned for post-diagnosis monitoring, they may have the potential as diagnostics or to expedite triage into secondary care. For the full list see Table S3.

While direct measures of lung function dominate the field of approved tests, there is a shift within the development pipeline to focus on indirect measurements of CRD, with *in vitro* diagnostics (19), breath analysis (17) and acoustic tests (14) dominating (Fig. 1A, Table 1).

Similar to the approved test landscape, most pipeline innovations concentrate on high-prevalence conditions such as asthma and COPD, with comparatively limited progress being made in the development of diagnostics for less common conditions, ILD and bronchiectasis.

Tests with regulatory approval for diagnosis (blue) or monitoring (yellow) and tests in the development pipeline intended for diagnosis (green) or monitoring (pink). (A) Distribution of tests by test classification. (B) Distribution of tests by disease indication. Disease indications reflect the corresponding GlobalData search results; some tests may be applicable to additional respiratory conditions beyond those shown. The number of tests in each section are shown, sections without numbers represent one test.

COPD, chronic obstructive pulmonary disease; ILD, interstitial lung disease (including idiopathic pulmonary fibrosis).

Table 1
Breakdown of the approved and pipeline test numbers in each test classification.

Test classification / Measurement type	Number of tests	
	Approved (n = 137)	Pipeline (n = 69)
Lung function	68	3
Spirometry	47	2
Peak flow	15	-
Oscillometry	3	-
Bronchial Hyperresponsiveness	1	-
Disease symptoms	1	-
Exhaled breath volume	1	-
Wearable	-	1
In-vitro diagnostics	15	19
Blood biomarkers	9	5
Blood and sputum biomarker	3	-
Sputum biomarker	2	3
Saliva biomarker	1	-
Bronchial biopsy analysis	-	2
Gut microbiome	-	1
Nasal swabs	-	1
Skin odours	-	1
Urine sample	-	1
Not specified	-	5
Breath analysis	14	17
FeNO	9	2
CO ₂ waveforms	1	-
Gas exchange	1	-
Lung oxygenation	1	-
Tidal breathing analysis	1	-

Test classification / Measurement type	Number of tests	
	Approved (n = 137)	Pipeline (n = 69)
Lung function	68	3
Volatile organic chemicals	1	10
Labelled CO ₂	-	2
Non-volatile biomarkers	-	1
Not specified	-	2
Acoustic	9	14
Medical device	3	1
Software	4	6
Wearable	2	7
Respiratory health monitor	7	5
Vitals	3	3
Imaging analysis	14	6
CT scan analysis	8	3
Diagnostic imaging	3	1
X-ray analysis	3	2
Pulse oximetry	7	2

Promising technologies to address the need in primary care

To address the diagnostic needs of primary care, tests must be capable of diagnosing CRD in the context of comorbidities, identifying conditions with overlapping symptoms, be acceptable to patients, and integrate seamlessly into clinical workflows, whilst considering the logistical elements of the primary care setting. The specific requirements for tests aimed at accelerating diagnosis of CRD in the primary care setting are outlined in a published target product profile[11].

Two active areas of the pipeline - breath analysis and acoustic technologies - show promise in addressing this unmet need. Here, we present our analysis of these modalities with a focus on the strengths, weaknesses, opportunities and threats.

Breath analysis and breathomics

Breath analysis and breathomics, (the analysis of volatile organic compounds (VOCs), involves the characterisation of biomarkers in exhaled breath. This is based on the hypothesis that their composition

and relative abundance reflect the underlying physiological and pathological processes within the respiratory system[25]. Biomarkers can include VOCs (hydrocarbons, ketones and aldehydes), non-volatile constituents (metabolites, lipids and proteins), and small inorganic molecules (nitric oxide, oxygen and carbon dioxide). Breath analysis and breathomics are an established but rapidly evolving field for respiratory diagnostics and have several characteristics which could make them suitable for use in primary care (Table 2).

14 breath analysis tests currently have regulatory approval (Fig. 1A), the most common being fractional exhaled nitric oxide (FeNO) devices, a diagnostic test for asthma. In Europe, 3 devices measuring other exhaled breath makers (CO₂ waveforms or exhaled VOCs) have regulatory approval but are not yet used in routine clinical care (Table S2). In the development pipeline there are 17 breath analysis tests (Fig. 1A, Table S3), most of these are being developed to detect asthma and/or COPD, with one test in development for asthma, COPD and ILD. Other innovations in the pipeline include the detection of breath nitrite, which may be more accurate than FeNO for diagnosing asthma[40] and the use of ¹³C-labelled urea to detect ¹³CO₂ in the breath to diagnose COPD and post-covid bronchiectasis[41].

Table 2

SWOT analysis of breath analysis technologies as diagnostic tests for chronic respiratory disease.
Summary of the strengths, weaknesses, opportunities and threats associated with the use of breath analysis technologies for the diagnosis of chronic respiratory disease.

Strengths	Weaknesses
• Effort independent • Non-invasive • Quick sample collection • Low level of technical expertise required (depending on equipment type) • Longitudinal measurements are possible • Clinical evidence suggests breathomics may be able to distinguish between disease types[26–30] and subtypes[31].	• Exhaled biomarkers can be influenced by cofounding factors: age, comorbid conditions, BMI, or other exogenous factors (smoking, pollution, medications)[32]
Opportunities	Threats
• Marketed devices available for lung cancer and COVID-19 diagnosis • Results could inform clinical decision making • Potential to identifying the inflammatory phenotypes in asthma patients, thereby expediting triage of patients into secondary care[33, 34] • Potential application in disease monitoring and predicting exacerbations[35–37] • Potential use in both adult and paediatric populations	• Clear guidelines and standardised methods are needed for widespread adoption[38]. • Sensor drift may impact the test accuracy, advances in AI/ML analysis algorithms may be able to compensate for this phenomenon[39].

Breath analysis and breathomics is based on the concept that lung biology influences the composition of exhaled breath, producing biomarker patterns specific to biological processes and diseases. Typically, they are non-invasive, quick and easy to perform using normal tidal breathing, characteristics which could make them more acceptable for people with CRD than tests requiring forced exhalation. There is also some clinical evidence that breathomics may be able to distinguish between CRDs (asthma, COPD, ILD, lung cancer) and different subtypes (ILD, asthma) [24–29] which would make them valuable during the early stages of diagnosis. However, there are number of weaknesses and threats which could hinder this technology. VOC profiles can be influenced by patient characteristics (age, BMI) or external factors (smoking, pollution, or medications)[32]. Therefore, reliable reference data and guidelines will be required.

Acoustic analysis

Acoustic signatures e.g. coughs, wheezes, and crackles are key symptoms of respiratory conditions[42, 43]. Advancements in sound detection and analysis, alongside the increase of wearable devices and AI technology now facilitate novel ways to collect and interpret respiratory sounds[44].

Nine acoustic products have regulatory approval with the majority designed for remote monitoring of a diagnosed CRD (Fig. 1A, Table S2). Two have regulatory approval for the diagnosis of asthma and/or COPD, although there is no evidence of them being integrated into clinical care for these conditions. There are 14 acoustic tests in the developmental pipeline and most of these are also indicated for asthma and/or COPD (Fig. 1A, Table S3). None are explicitly intended for bronchiectasis or ILD, although one device in the pipeline is being developed for monitoring of asthma, COPD and IPF.

Acoustic technologies have potential as low effort point-of-care diagnostic tests or remote monitoring tools (Table 3). They are often integrated into smartphone application or wearable technology meaning they could increase patient accessibility and compliance. Additionally they can allow longitudinal monitoring of symptoms and there is evidence to suggest acoustic signals are capable of detecting exacerbations earlier than patient reported symptoms[45]. The analysis of acoustic data often makes use of AI to interpret the sound data and translate them into disease signatures, which could unpick overlapping symptoms. However, a potential threat to their development is a lack of validated datasets to train the AI models, with some evidence suggesting that models do not translate to real-world use[46], and a need for rigorous and well-designed clinical studies when determining their diagnostic value[47]

Table 3

SWOT analysis of acoustic analysis technologies as diagnostic tools for chronic respiratory disease.
Summary of the strengths, weaknesses, opportunities and threats associated with the use of acoustic analysis technologies for the diagnosis of chronic respiratory disease.

Strengths	Weaknesses
• Non-invasive • Cost-effective and accessible (depending on technology) • Potential for real time analysis and quick time to results • Effort independent (depending on measurement type)	• Strength of biomarker requires further clinical validation for diagnosis[46, 47]. • Data quality is dependent on the sound recording equipment and background environment[47, 48] • High-quality, labelled lung sound datasets are limited due to variability in recording environments and equipment. • AI/ML algorithms can lack explainability and interpretability.
Opportunities	Threats
• Rapidly developing field with potential for point-of-care diagnostics and remote monitoring • Potential for longitudinal measurements • May enable remote detection of disease and establish individual baselines • Could guide treatment decisions and predict exacerbations • Potential use in both adult and paediatric populations	• Training datasets need to be high quality, annotated, and universalizable[49]. • External variables may confound real world use e.g. background sounds or seasonal effect on cough symptoms • Data privacy, model transparency, and appropriate clinical validation will be required for regulatory approval

Discussion

In reviewing the landscape of diagnostic and monitoring tests for CRD, we identified 137 diagnostic tests in our scope that have regulatory approval and 69 tests within the developmental pipeline.

Unsurprisingly, the approved landscape was dominated by lung function tests and whilst these can provide valuable information there are barriers to their routine use in primary care, such as training requirements and poor accessibility[16, 17]. Additionally, they can be challenging for patients with CRD to perform due to the physical effort required for the forced exhalation manoeuvres[18].

Contrastingly, the pipeline represents a shift towards indirect measurements of lung function and CRD, which offers potential advantages over traditional diagnostic tests. Although we note the challenges associated with achieving robust sampling and reproducible measurement of breath and acoustic biomarkers, we recognise the potential such technologies have in both identifying complex disease signatures and meeting the requirements of primary or community care settings (e.g. ease of use, greater accessibility).

Implications for innovators and developers

Our review highlights several promising technologies that could meet the needs of CRD patients and the primary care setting. Advances in breath analysis, breathomics, acoustics and wearable sensors may offer opportunities for minimally invasive tests that do not rely on forced exhalation. In parallel, AI and machine learning approaches have the potential to unpick complex biological signatures and create diagnostic tests which do not need extensive processing and specialist interpretation making them more translatable to primary care. Further, there is a commercial opportunity with the rising prevalence of CRD, the global respiratory diagnostics market is predicted to grow from US\$6.17 billion in 2025 to US\$9.02 billion in 2030[50].

Strengths and weaknesses

This review provides a representative overview of the respiratory diagnostic market. The approach provides a structured overview of current and emerging technologies across multiple test modalities relevant to use in primary care and specialist settings.

It is important to note that our search relied on a single market intelligence database. Market intelligence databases vary in their completeness, and gaps can occur, particularly in rapidly evolving fields. As a result of this, minor amendments were therefore made based on author knowledge where appropriate. Additionally, the developmental pipeline analysis was restricted to the USA and Europe (including the UK). This was a deliberate methodological choice to support a focused assessment of technologies within regulatory and healthcare contexts most relevant to author's experience and translational remit. As a result, emerging technologies in other global regions may not have been captured and should be considered in future analyses.

We conducted in-depth analyses of breath analysis and acoustic technologies because these approaches demonstrate favourable attributes for use in primary care and show high levels of activity across the development pipeline. However, other test types may also hold future promise either through further technological advancement or repositioning for use earlier in the diagnostic pathway.

Conclusions

In conclusion, while the diagnostic landscape for CRD continues to evolve, sustained innovation is needed to address the significant unmet need[6, 7]. This landscaping analysis provides a practical resource for developers, funders, and decision-makers to identify technologies that are ready for acceleration into clinical practice, those with potential for repositioning, and critical gaps where new solutions are required. As diagnostic pathways increasingly shift towards community-based settings, including diagnostic centres and pharmacies, it is essential that new technologies are designed with these environments in mind. Finally, aligning innovation with the needs of end users and the realities of clinical settings will be key to enabling seamless adoption and maximising the impact of future diagnostic solutions.

Declarations

Author contributions

Sam Warburton designed and conducted the GlobalData searches, analysed the data, prepared the figures and contributed to drafting the manuscript. Sarah Williams analysed the data, prepared the figures, interpreted the findings, drafted and revised the manuscript. Mandy Tseng conducted the GlobalData searches and analyses. Kile Green and Erika Kennington co-developed the research question and contributed to drafting and reviewing the manuscript. Rebecca Holmes co-developed the research question, interpreted the findings and contributed to drafting and reviewing the manuscript. Samantha Walker contributed to the study concept, contextual interpretation of the findings and critically reviewing the manuscript. All authors reviewed and approved the final version of the manuscript.

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Figures

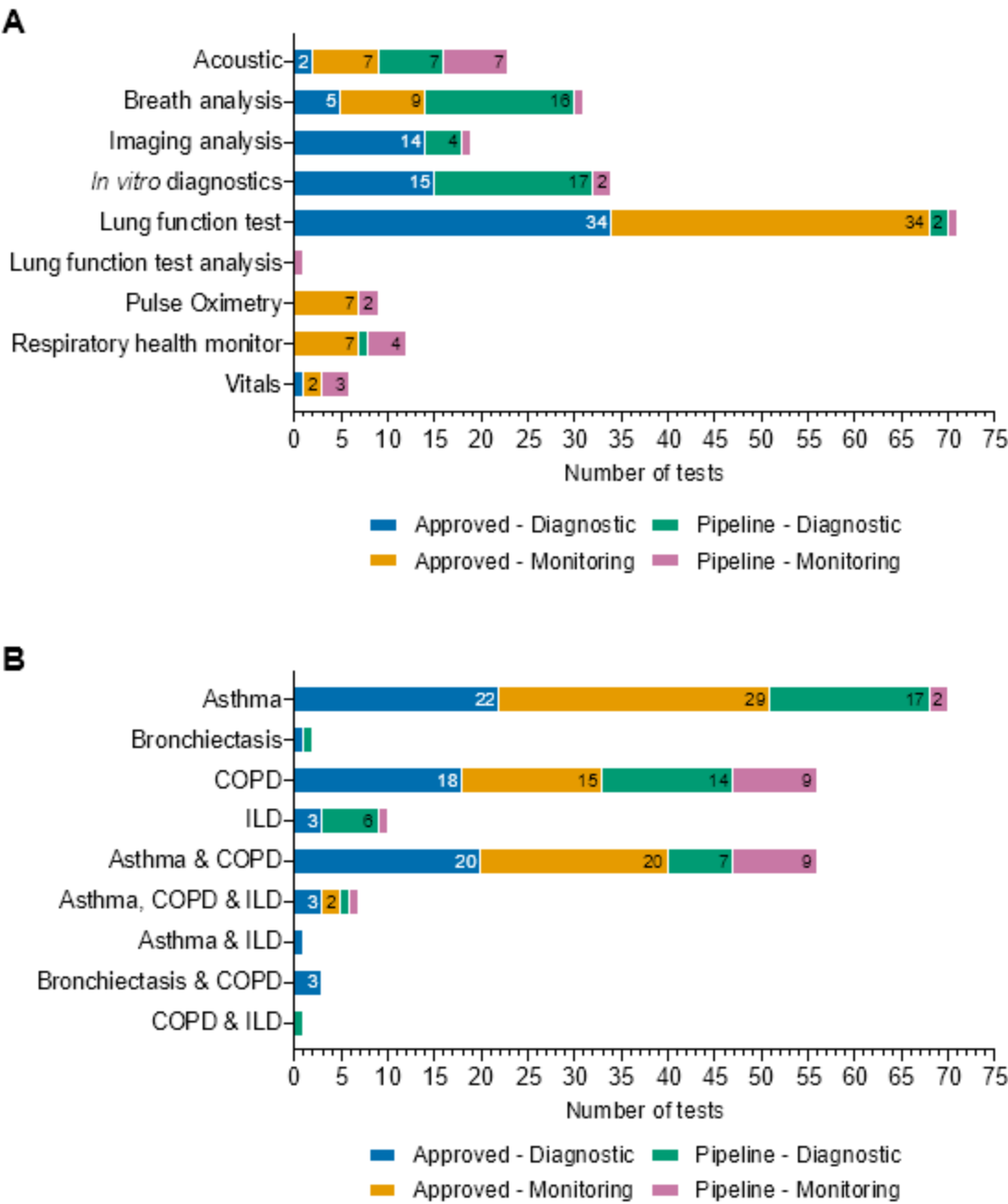


Figure 1

Overview of the diagnostic and monitoring test landscape for chronic respiratory disease.

Tests with regulatory approval for diagnosis (blue) or monitoring (yellow) and tests in the development pipeline intended for diagnosis (green) or monitoring (pink). (A) Distribution of tests by test classification. (B) Distribution of tests by disease indication. Disease indications reflect the

corresponding GlobalData search results; some tests may be applicable to additional respiratory conditions beyond those shown. The number of tests in each section are shown, sections without numbers represent one test.

COPD, chronic obstructive pulmonary disease; ILD, interstitial lung disease (including idiopathic pulmonary fibrosis).

Supplementary Files

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