

VocalisHealth

VocalisTrack

Voice Platform for Detection
of Shortness of Breath



VocalisTrack: A Voice-Based Tool for Remote Detection of Shortness of Breath

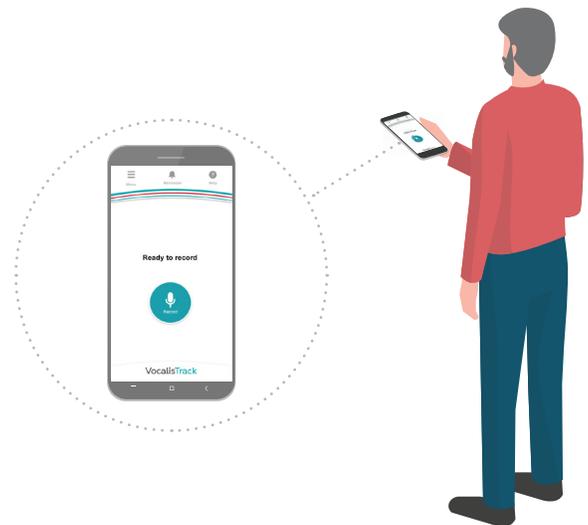
VocalisTrack is a stand-alone, AI-based software device that analyzes voice recordings of COPD patients.

- Passive using patient's own voice
- Uses patient's smartphone without additional hardware or physical examination
- Detects shortness of breath
- Bridges the gap between the patient and the healthcare system

PATIENT EASE OF USE

A user-friendly smartphone app prompts the patient to record his or herself, without the need for additional hardware or physical examination.

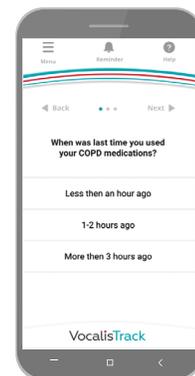
The app then uploads the voice recordings to the secure cloud platform, where the recordings' quality is verified and analyzed by the VocalisTrack proprietary AI based algorithm. If the quality is insufficient, the patient will be asked to record again.



Passive using patient's own voice

PATIENT DIARY

In addition, VocalisTrack allows the patients to manage a diary of their symptoms, a digital chart of common symptoms of COPD. The symptoms are self-reported by the patients and not used by the algorithm for detection of shortness of breath.



Uses patient's smartphone without additional hardware or physical examination

PROVIDER DASHBOARD

The output is displayed to the clinical team on a web-based dashboard as one of three categorical results:

- 1) Worsening or
- 2) Improvement or
- 3) No change in the current level of shortness of breath compared to previous recordings.



Patient status display on provider dashboard

This enables the clinical team to review the patients' status on a daily basis and potentially approach the patient once the app detects shortness of breath.



Detects shortness of breath

CLINICAL VALIDATION

Results from the retrospective performance evaluation study demonstrated high accuracy of the VocalisTrack device, with 93.51% agreement rate between the VocalisTrack conclusion and physicians' assessments (ground truth) on a cohort of diagnosed COPD patients (n=77).*

The sensitivity and specificity for identifying change in shortness of breath compared to clinicians' assessments were 95.45% (95% CI: [77.16%, 99.88%]) and 92.73% (95% CI: [82.41%, 97.98%]), respectively.

The confusion matrix below shows the prediction accuracy for the VocalisTrack algorithm trained to identify changes in shortness of breath (worsening, no change or improvement), compared to physicians' assessments (ground truth).

Ground Truth Physicians' Assessments	BETTER	0	3	25
	SAME	1	21	0
	WORSE	26	1	0
		WORSE	SAME	BETTER
		Vocalis Track Detection		

*Data on file

The Significance of Shortness of Breath

Shortness of breath, also termed dyspnea, is reported by COPD patients to be the most disruptive symptom, and the primary reason for patients to seek medical care. Dyspnea is the term generally applied to sensations experienced by individuals who complain of unpleasant or uncomfortable respiratory sensations.¹

Dyspnea levels reported by COPD patients have been demonstrated to predict general health status, exercise performance after pulmonary rehabilitation and quality of life.^{2,3,4} Dyspnea is also a predictor of readmission and mortality,^{5,6} including risk of 3-month readmission in COPD patients surviving COPD-related acute hypercapnic respiratory failure (AHRF).⁷ Dyspnea severity was also associated with poorer health related quality of life (HRQOL) scores and decreased physical performance.⁸

There are no existing tools today to directly and objectively measure the level of dyspnea.⁹ Several scales, such as mMRC, have been employed to

measure dyspnea, but they rely on patients' answers to questionnaires and hence are prone to biases. Other tools such as the six-minute walk test or measuring oxygen saturation to detect hypoxemia can be used to detect dyspnea indirectly.

Given the significance of dyspnea in COPD progression and the lack of tools to directly measure its level remotely, we developed a unique and innovative tool to allow the clinical team to detect dyspnea remotely in COPD patients. While the impact of VocalisTrack on COPD outcomes has not yet been studied, it potentially could improve the clinical pathway for the patient. This is yet to be demonstrated.

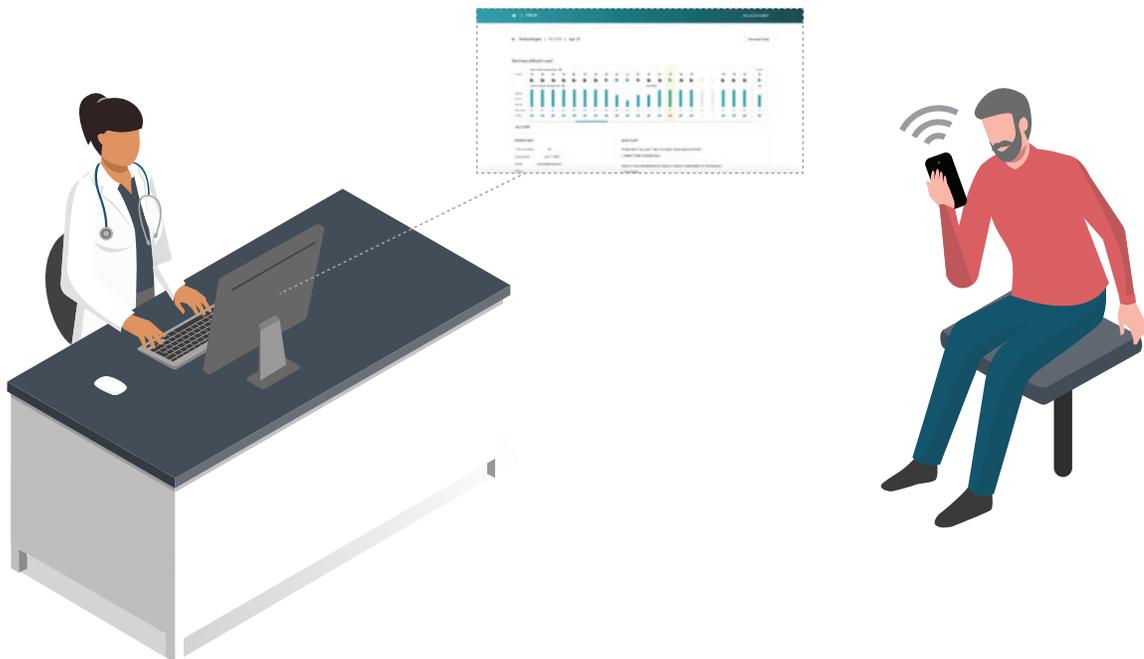
Improving the Clinical Pathway

Patients that were recently hospitalized with a COPD exacerbation often do not follow their post discharge instructions, for various reasons. As a result of this lack of compliance, they frequently present to the ER and end up readmitted. Unfortunately, their clinical care team had no way to track their status.



VocalisTrack offers the clinical care team additional insight about the patient's current shortness of breath. The patient uses the app on his own smartphone. The daily reminder prompts the patient to record his voice and answer a few simple discovery questions. Now the care team can check

the dashboard daily to see if the patient's shortness of breath has improved, worsened or stayed the same. If the dyspnea worsens, now the care team can initiate contact with the patient and potentially take clinical actions according to the standard of care to positively impact his health.



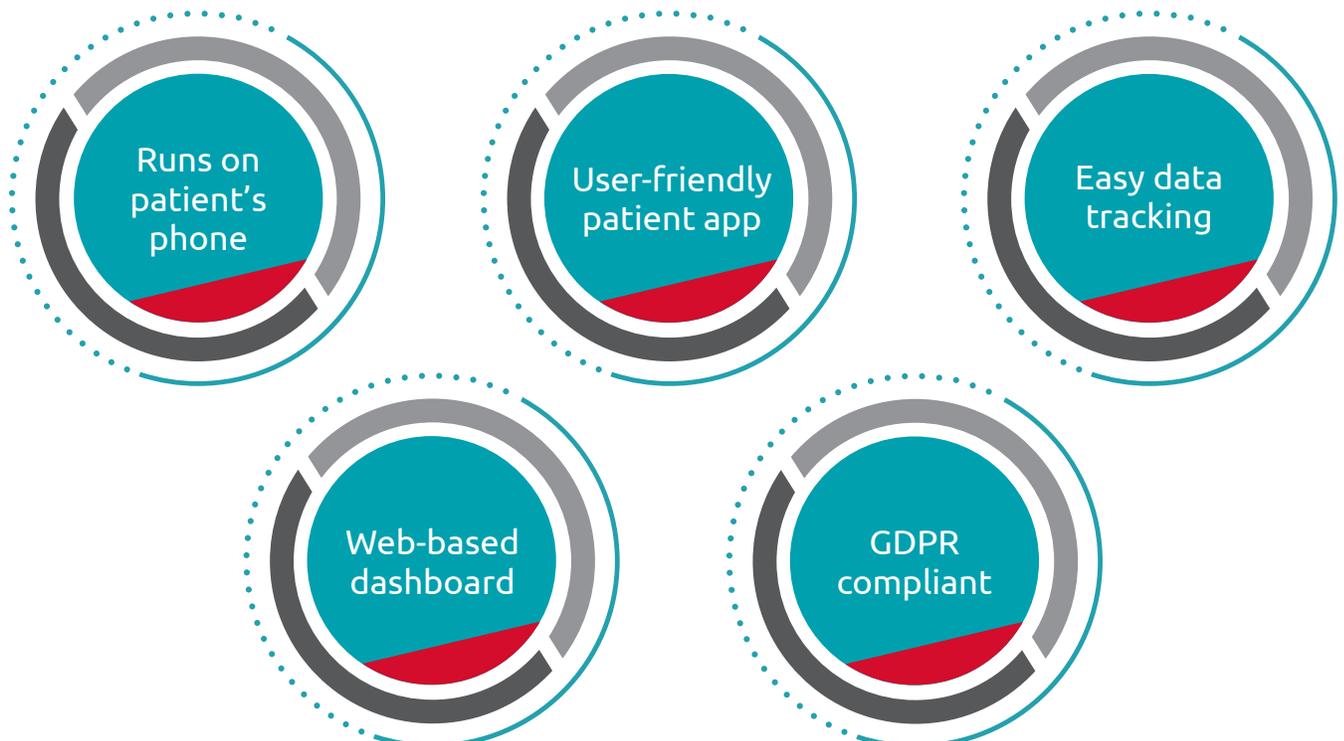
Bridges the gap between the patient and the healthcare system

The Economic Burden of COPD

COPD is a very common chronic disease, with 18 million diagnosed COPD patients in the US alone.¹⁰ In Europe, the prevalence of COPD varies from 4-10% of the adult population.¹¹ About one-third of these patients are considered severe (GOLD categories C and D), and many of these patients suffer from COPD exacerbations several times a year.¹² Discharged COPD patients are at increased risk of readmission, with a 20% risk in 30 days and 40% in 1 year. In fact, COPD is 1 of 3 voice-affecting diseases, along with heart failure and pneumonia, that rank among the top 5 causes of 30-day readmissions. Yet, up to 55% of readmissions after a COPD hospitalization may be preventable.¹³

As noted in a recent study,¹⁴ COPD places a significant burden on patients and healthcare systems,^{15,16} in particular, exacerbations, which account for the majority of hospital admissions for COPD patients.^{17,18} Health care resource utilization (HCRU) is measured in registry-based studies by

hospitalizations and out-patient visits in order to describe the burden of the disease.¹⁹ A study based on registry data from Sweden demonstrated that patients with a history of severe exacerbations and high use of medication for COPD had an increased rate of exacerbations and HCRU.²⁰ As a result, the economic burden of the disease is substantial, and given the ageing populations in many countries, it is likely to continue to rise over time. For example, annual COPD-related costs in Finland have been predicted to rise by 60% between 2007 and 2030 to €166 million and annual direct COPD-related costs in the USA have been predicted to increase to \$49 billion in 2020.^{21,22} Across Europe in 2011, the total annual direct health care costs of COPD for inpatient and outpatient care, primary care (PC), and drug costs were estimated to be €23.3 billion.²³ In Denmark, COPD bears an annual net cost of €8,572 per patient.²⁴ Given the economic burden of COPD worldwide, the need for a tool to detect dyspnea remotely is clear.



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The voice of healthcare



VocalisHealth

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