

Continuous Cough Monitoring For Early Detection Of COPD Exacerbations Using Hyfe: Interim Results From A Prospective Multi-center Cohort Study

F. S. Carrión-Nessil¹, M. Rubio², F. Gammella³, A. Alvarado⁴, J. P. De Torres³, J. Bartolomé², J. Brew⁵, M. Galvosas⁵, P. M. Small⁵, C. Chaccour¹;

¹Institute for Culture and Society-NCID, Universidad de Navarra, Pamplona, Spain, ²Centro de Salud de Ardoi, Servicio Navarro de Salud-Osasunbidea, Pamplona, Spain, ³Clinica Universidad de Navarra, Pamplona, Spain, ⁴Clinica San Miguel, Pamplona, Spain, ⁵Research and Development Department, Hyfe Inc., Wilmington, DE, United States.

Rationale

COPD exacerbations drive disease progression, hospitalization, mortality and drug development, yet detection remains limited and relies on subjective symptom reporting. Cough, a hallmark symptom of COPD, may provide an objective, continuous biomarker for exacerbations. However, longitudinal cough patterns in COPD have never been characterized using continuous 24/7 monitoring. We present interim findings from an ongoing prospective study evaluating passive cough monitoring using the Hyfe CoughMonitor, a validated AI-powered wearable system, to characterize cough variability in COPD and assess its potential for exacerbation detection.

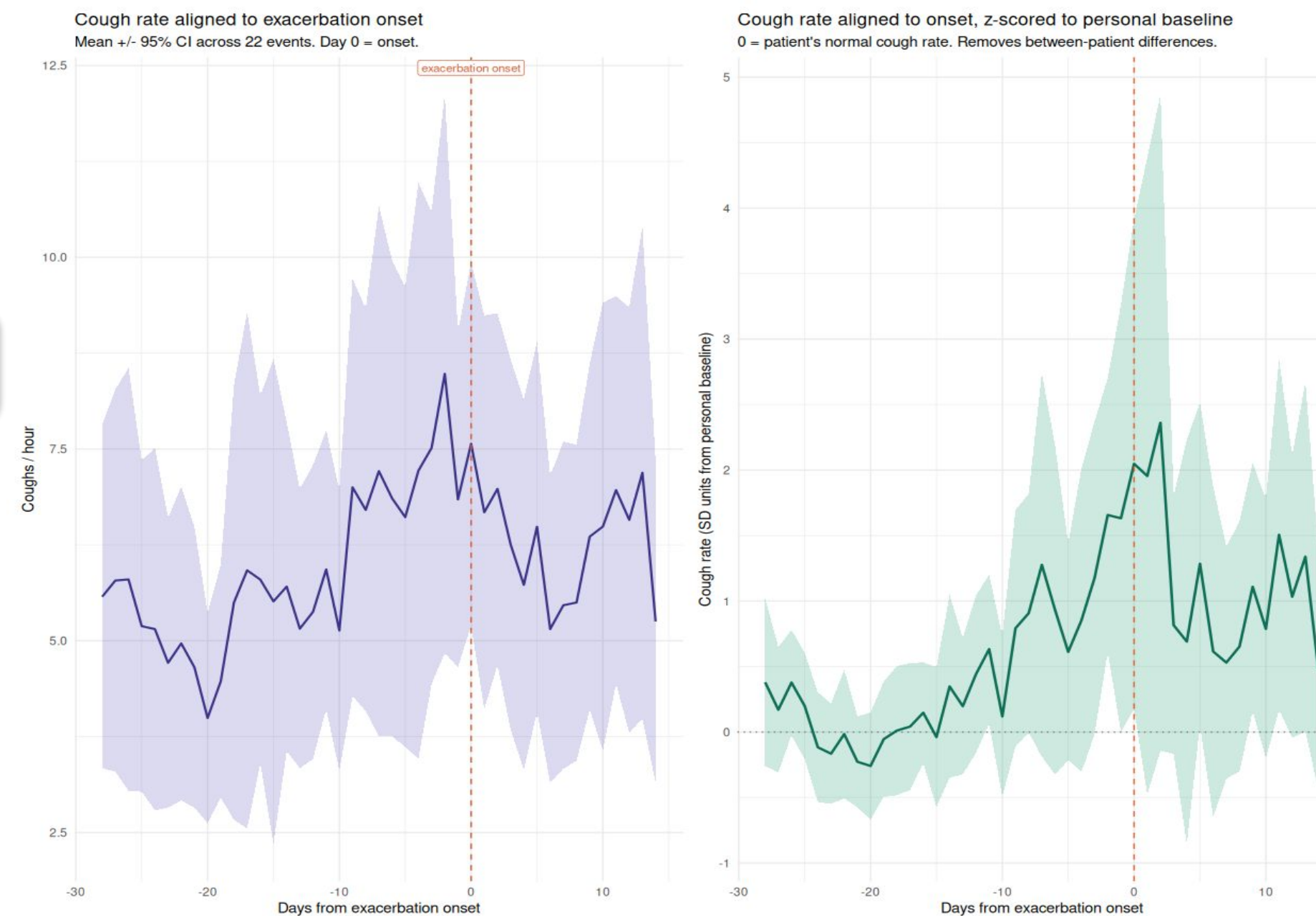
Methods

This **prospective, multi-center, observational cohort study** (NCT07212439) recruits COPD patients across clinical sites in Navarra, Spain. Participants wear the Hyfe CoughMonitor during waking hours and charge it bedside overnight, where it continues cough monitoring. **Weekly CAT questionnaires** and paraclinical data supplement cough monitoring. Clinicians and patients are blind to cough rates and study-administered CAT scores; exacerbation diagnosis follows standard care using GOLD 2025 criteria. We report **interim analyses** of cough rate variability and temporal patterns surrounding clinically confirmed exacerbations.

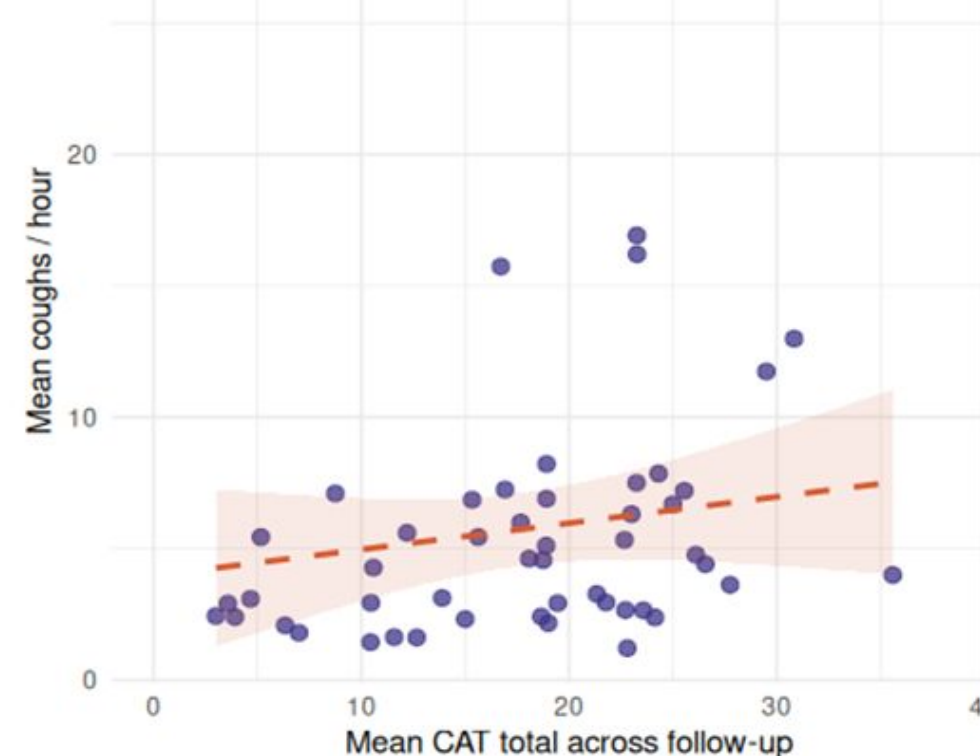
Results

- Data as of May 2026, 50 participants, 110,000 patient-hours of monitoring encompassing over 610,000 coughs (average rate = 5.56 per monitored hour), 22 exacerbations
- There have been 22 exacerbations. There is a clear spike in the mean hourly cough rate in the 10 days preceding the exacerbations with up to 33% more coughs measured in the 3 days before the diagnosis
- A model of cough in the last 7 days (normalized to the person's baseline via z score) predict an exacerbation in the next 7 days with an AUC of 0.62
- There is a weak correlation between the overall CAT scores and the weekly cough rates as well as with the CAT question one ("How was your cough this week? 0 = I never cough, 5 = I cough all the time")

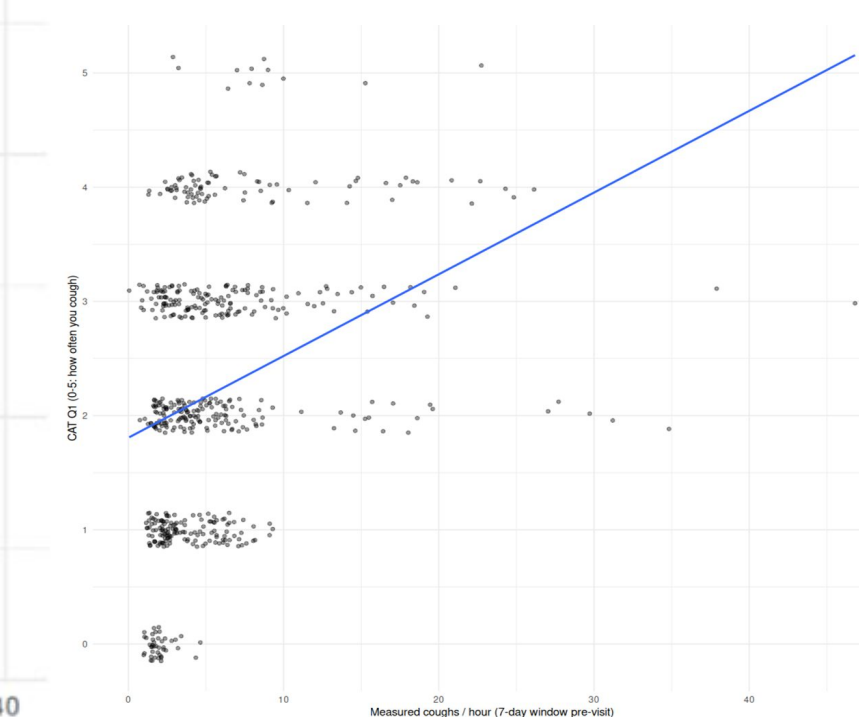
50 participants, 110,000 patient-hours of monitoring encompassing over 610,000 coughs (average rate = 5.56 per monitored hour), 22 exacerbations.



Per patient CAT score vs measured coughs



Perceptio (CAT Q1) vs measurement



Conclusions

Continuous objective monitoring for 110,000 patient hours reveals **substantial cough variability** in COPD that frequently diverges from subjective patient perception and CAT scores. **Cough frequency notably increases during the 14-day period preceding exacerbations.** An individualized rolling seven-day baseline model shows potential for forecasting exacerbations. Continuous cough monitoring is a promising digital biomarker for the early detection of COPD exacerbations

Take-Home Points

1. COPD patients show excellent adherence to continuous cough monitoring and weekly CAT questionnaires
2. There is substantial variation in cough rates ranging from 0 to 1,451 coughs in one day
3. Cough rates spike in the 10 days leading to an exacerbation and the 7-day rolling average of cough rates can predict these events with an AUC of 0.62
4. CAT questionnaires and subjective cough perceptions are weekly correlated with actual cough rates
5. Monitoring may increase accuracy of exacerbations in clinical trials

Contact:
Peter M. Small, M.D.
Chief Medical Officer
peter@hyfe.com



Disclosures: PMS, MR, JB and MG are employees and own equity in Hyfe Inc. CCh owns equity from Hyfe Inc. Funding: Hyfe Inc.