

Validation of an automated, fully on-device cough monitoring wearable

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BACKGROUND

The ability to passively and continuously monitor cough improves cough management and research. The Hyfe Cough Diary (HCD) is a smartwatch with a fully on-device signal-processing and machine-learning system which detects and timestamps coughs in real-time, with no audio recording or retention. Here we describe the clinical validation of the device's accuracy on 31 patients in real-world settings, where device-generated hourly cough counts were compared with ground truth counts generated by expert annotators.

METHODS

We collected 20–24 hours of continuous sounds from each of 31 adult subjects while they wore the HCD and went about their usual daily activities. The watch was charged <3 ft by the bedside at night while counting coughs. Expert annotators reviewed the continuous audio collected from a separate device and noted the exact time of every cough (ground truth). The times of the device-detected coughs were compared with the times of cough per ground truth so as to determine the system's performance. Accuracy was assessed for the entire group, for each subject, and for subsets using event-to-event and hourly rate correlation analyses.

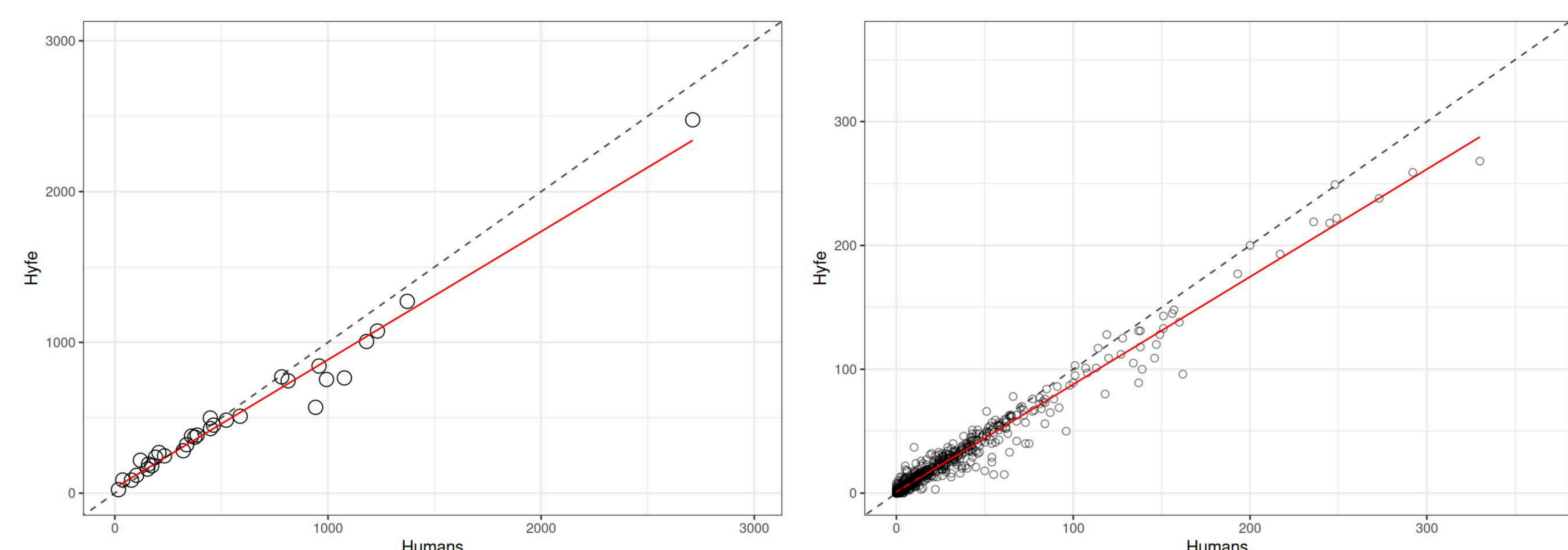
Pre-registration: <https://clinicaltrials.gov/study/NCT06775301>

Table 1. Demographic and operational information

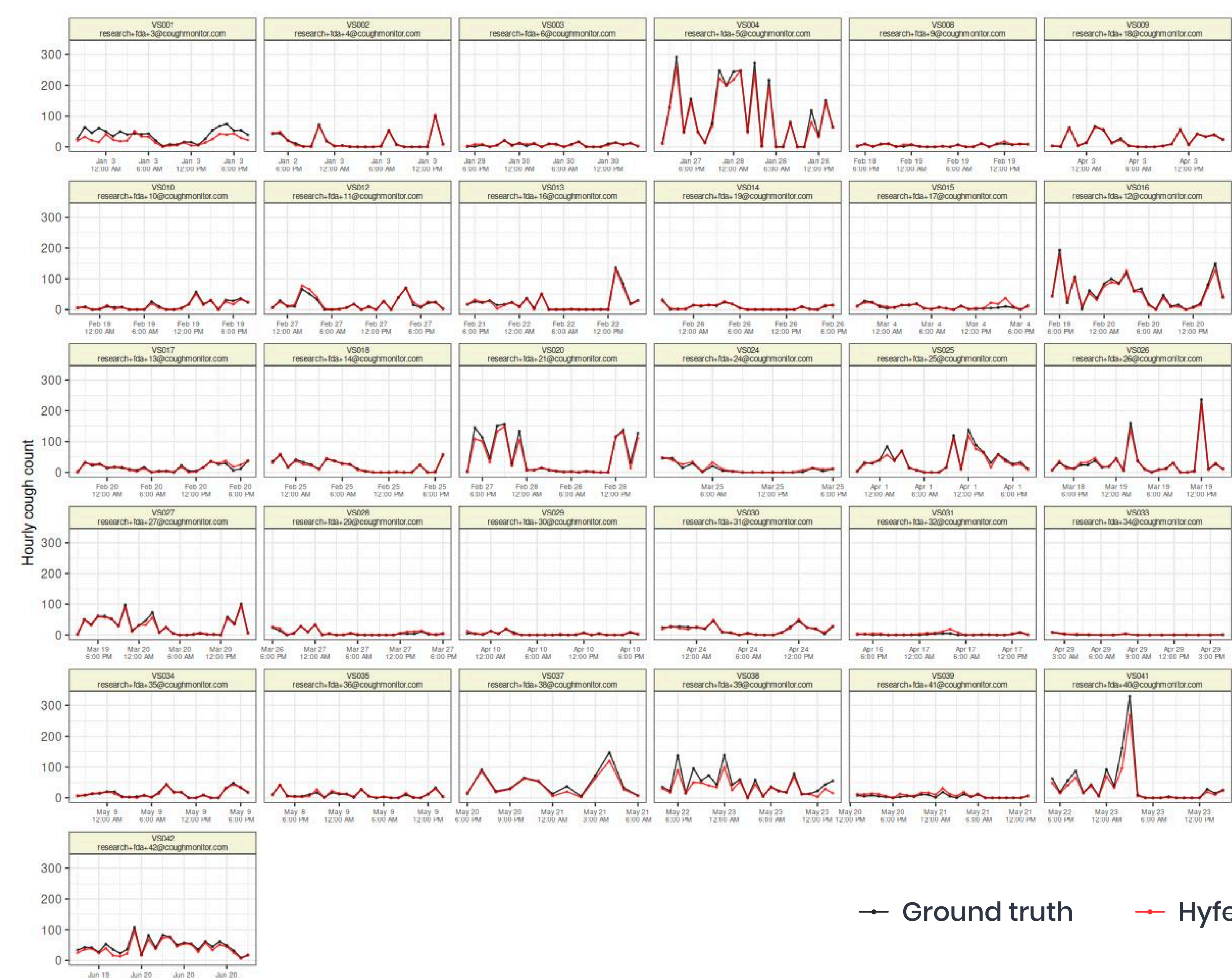
Participants	31
Person-hours	730.84
Hours removed due to participant indicating that one or more devices weren't worn	2.52 (0.34%)
Total ground truth coughs	18,305
Total device coughs	16,745
Participant population by etiology (not mutually exclusive):	
Acute cough	2
Allergies	2
Asthma	5
Bronchiectasis	4
GERD	4
Laryngeal Neuropathy	2
NTM	2
UACS	2
UCC	13
Participant demographic details:	
Age	57.2 (SD: 12.1)
Sex	23 females (74.2%)
Race / Ethnicity	28 white, 1 Asian, 1 African-American, 1 Hispanic

RESULTS

Median sensitivity to cough was 87%. Median false positive rate was 1.6 per hour. Agreement between each patient's total (24 hour) device cough counts and ground truth cough counts, as measured by the Lin's Concordance Correlation Coefficient (LCCC), was 0.958 (bottom left); for hourly counts, LCCC was 0.975 (bottom right).



The device demonstrated high accuracy and fidelity to trends with hourly counts from the device (red) closely matching ground truth (black) for all patients (below).



Sensitivity and false positive rate were not statistically significantly different across cough rate, sex, age, etiology, or urban-rural residence. Night-time and day-time sensitivities were nearly identical, with higher false positives during the day. Coughs which occurred in bouts (a bout being any string of coughs separated by fewer than 5 seconds) were correctly detected at a similar rate as singleton coughs. Using 4 groups by cough rate (<10, 10–20, 20–30, >30 per hour), the large majority (26 of 31, i.e. 84%) of participants' overall cough rates were correctly categorized by HCD. Miscategorization was rare (5/31; 16%) and always minor: two "low" coughers were classified as "medium-low," one "medium-low" as "medium-high," and one "high" as "medium-high."

TAKE-HOME POINTS

1. The Hyfe Cough Diary **accurately monitors coughing** in problematic coughers as they go about their usual daily activities.
2. The ability to continually and passively monitor cough has the potential to improve **patient care, cough research and drug development.**



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731
hours
monitored

**Real
World
Environments**

18k
cough
events

25
mean hourly
cough rate



87%
Median
sensitivity to
cough

0.975
Lin's Concordance
Correlation
Coefficient

1.6
false
positives / hr