Online Supplement

Pilot Study of a Patient Experience with an ELLIPTA Inhaler Electronic Medication Monitor and Associated Integrated System: A Prospective Observational Study Using the COPD Patient-Powered Research Network

Barbara P. Yawn, MD, MSc[1*,2] Gretchen M. McCreary, MA[1] John A. Linnell, BA[1] Cara B. Pasquale, MPH[1] Elisha Malanga, BS[1] Radmila Choate, PhD, MPH[1,3] David A. Stempel, MD[4*] Rahul Gondalia, PhD, MPH[5*] Leanne Kaye, PhD, MPH[5*] Kathryn A. Collison, MPH, PMP[4*] Benjamin S. Wu, PharmD, MS[4*] Daniel Gratie, PharmD[4*] Richard H. Stanford, PharmD, MS[4*] Ryan Tomlinson, MRPharmS, PhD[6]

[1]COPD Foundation, Miami, Florida, United States

[2]Department of Family and Community Health, University of Minnesota, Minneapolis, Minnesota, United States

[3]Department of Epidemiology, College of Public Health, University of Kentucky, Lexington, Kentucky, United States

[4]Respiratory Therapy Area, GlaxoSmithKline plc., Research Triangle Park, North Carolina, United States

[5]Propeller Health, Madison, Wisconsin, United States

[6]Respiratory Therapy Area, GlaxoSmithKline plc., Collegeville, Pennsylvania, United States

[*]*At time of study. RG and LK are currently employed by ResMed. KAC is currently employed by AstraZeneca. BSW is currently employed by United Therapeutics Corporation. DG and RHS is currently employed by AESARA. DAS is currently employed by Propeller Health.*

Description of Propeller Health EMM

Propeller Health is an FDA cleared self-management platform for COPD. The platform includes electronic medication monitors (EMM), a paired smartphone app, and a secure web dashboard for providers (**Supplementary Figure 1**). In this study, participants were asked to attach an EMM to their compatible inhaler medication and download the Propeller app to their smartphone. The EMM automatically tracked the date and time of each inhaler actuation and wirelessly transmitted the data via Bluetooth to the paired app. Participants could view their medication usage data in the app, as well as view evidence-based COPD educational materials on symptoms and triggers. Participants also received audio/visual medications reminders through the EMM and app, and app and/or email notifications for poor adherence or increased rescue medication use from baseline based on their self-reported prescribed medications.

Supplementary Figure 1. ELLIPTA inhaler with Propeller EMM attachment

The Propeller EMM attaches to the ELLIPTA inhaler to track medication usage. Data collected by the EMM is sent wirelessly via Bluetooth to a paired smartphone app.

Supplementary Table 1. Description of study variables and method of assessment

Variable category	Description

Demographics at baseline	• Age
	• Sex (female, male, other, prefer not to answer)
	• Race
	  ○ White, Black or African American, American Indian, Asian, or other
	• Ethnicity
	  ○ Hispanic/Latino or non-Hispanic/non-Latino
	• Height (for BMI calculation)
	• Weight (for BMI calculation)
	• BMI (underweight [<18.5], normal [18.5–24.9], overweight [25–29.9], or obese [≥30])
	• Asthma (concomitant asthma diagnosis)
	• Alpha-1 antitrypsin deficiency
	• Duration of COPD in years
	• Smoking status
	  ○ Current smoker
	  ▪ Pack year history
	  ○ Former smoker
	  ▪ Pack year history
	  ○ Never smoker (<100 cigarettes in lifetime)

Drug therapy at time of enrolment	Information was collected using pictures for identification of current therapies (in drug classes) and participant-entered drug information, and reclassified into categories as listed below.
	• Maintenance inhalers
	  ○ LAMA
	  ○ LABA
	  ○ LAMA/LABA

	○ ICS/LABA ○ ICS/LABA+LAMA • Rescue inhalers ○ SABA ○ SAMA ○ SABA/SAMA ○ Nebulized rescue use • Supplemental oxygen therapy • OCS • Oral therapy ○ Methylxanthines ○ PDE-4 inhibitors
CAT and exacerbation history at baseline	• CAT score • Self-reported exacerbation history over past 12 months ○ Total number of events of worsening of COPD symptoms for which the patient: ▪ Received oral corticosteroids or antibiotics in clinic, ED or urgent care ▪ Was hospitalized overnight for COPD symptoms
Exacerbation rates	Exacerbations rates were summarized using four categories: 1) Exacerbation requiring overnight hospital stay 2) Exacerbation requiring ED visit and steroid and/or antibiotic but no overnight hospital stay 3) Exacerbation requiring steroid and/or antibiotic, but no ED visit and overnight hospital stay 4) No exacerbations requiring steroids or antibiotic, no ED visit, and no overnight hospital stay A moderate COPD exacerbation was defined as: • An exacerbation requiring ED visit and steroid or antibiotic but no overnight hospital stay; or • An exacerbation requiring steroid and/or antibiotic, but no ED visit or overnight hospital stay A severe COPD exacerbation was defined as: • An exacerbation requiring overnight hospital stay

	Participants were assigned a GOLD A to D grade based on self-reported exacerbation history over the past year and CAT score as outlined in GOLD 2021.[1]

BMI = body mass index; CAT = COPD Assessment Test; COPD = chronic obstructive pulmonary disease; ED = emergency department; GOLD = Global Initiative for Chronic Obstructive Lung Disease; ICS = inhaled corticosteroid; LABA = long-acting β_2-agonist; LAMA = long-acting muscarinic antagonist; OCS = oral corticosteroids; PDE-4 = phosphodiesterase 4; SABA = short-acting β_2-agonist; SAMA = short-acting muscarinic antagonist.

Supplementary Table 2. Exit survey response

	Mean	SD	Median
For the ELLIPTA inhaler with sensor attachment (n=117)			
To what extent do you agree or disagree that…			
Reminders from the app made it easier to take my medication on time	4.25	1.13	5
I liked having reminders to use my ELLIPTA inhaler	4.33	1.10	5
I was able to use my ELLIPTA inhaler normally with the sensor attached	4.65	0.98	5
I feel confident using the sensor	4.56	1.05	5
I would recommend the sensor for other people with COPD	4.52	0.94	5
For the Propeller Health App (n=116)			
I found the app easy to use	4.63	0.80	5
The app helped me manage my COPD	4.20	1.01	5
I now feel more confident taking my medication on time	4.20	1.02	5
I now understand my COPD better	4.22	0.95	4.5
Overall, how satisfied are you with…. (n=116)			
The sensors (ELLIPTA inhaler and rescue inhaler)	4.49	0.84	5

The mobile app	4.48	0.77	5
The overall system (sensors and app)	4.08	1.14	4.5
How would you describe your experience (very difficult to very easy)			
Attaching the sensor onto the ELLIPTA inhaler (n=116)	4.53	0.75	5
For the rescue sensor (only 51 people had rescue sensor)			
I was able to use my rescue (quick relief) inhaler normally with the sensor attached (n=44) *	4.66	0.89	5
I would recommend the rescue sensor for other people with COPD **	4.41	1.06	5
Attaching the sensor onto the rescue inhaler (n=46) ***	4.72	0.62	5
Overall setting up the sensors and mobile app (n=116)	4.59	0.66	5

*n=44 participants responded on this exit survey question (out of n=51 using rescue inhalers)
**n=43 participants responded on this exit survey question (out of n=51 using rescue inhalers)
***n=46 participants responded on this exit survey question (out of n=51 using rescue inhalers)

Supplementary Table 3. Participants' COPD therapy at baseline (N=122)

Maintenance therapy	**n (%)**
INCRUSE ELLIPTA (LAMA)	9 (7.4)
ANORO ELLIPTA (LAMA/LABA)	20 (16.4)
BREO ELLIPTA (ICS/LABA)	25 (20.5)
TRELEGY ELLIPTA (ICS/LAMA/LABA)	58 (47.5)
Combinations:	
BREO ELLIPTA + INCRUSE ELLIPTA (ICS/LABA+LAMA)	7 (5.7)
ANORO ELLIPTA + TRELEGY ELLIPTA (LAMA/LABA + ICS/LAMA/LABA)	2 (1.6)
BREO ELLIPTA + INCRUSE ELLIPTA + TRELEGY ELLIPTA (ICS/LABA+LAMA+ICS/LAMA/LABA)	1 (0.8)
Rescue therapy	
SABA	51 (41.8)
Oral therapies	
Oral corticosteroids other than PRN	13 (10.7)

Antibiotics regularly	29 (23.8)
Methylxanthines	3 (2.5)
PDE-4 inhibitors	15 (12.3)
Supplemental oxygen therapy	
Yes	89 (73.0)
PRN	4 (3.3)
Daytime and nighttime	54 (44.3)
Only at night	22 (18.0)

COPD = chronic obstructive pulmonary disease; ICS = inhaled corticosteroid; LABA = long-acting β_2-agonist; LAMA = long-acting muscarinic antagonist; PDE-4 = phosphodiesterase 4; PRN = as required, not continuous; SABA = short-acting β_2-agonist.

Supplementary Table 4. Daily active use of the EMM-associated app, by CAT score, over the 24-week study period

	Baseline CAT score			
	10 (n=6)	**10–<20 (n=45)**	**20–<30 (n=54)**	**≥30 (n=17)**
PH app				
Daily active use (% of total for category)				
Days 1–7	61.9	67.6	70.6	74.0
Days 1–30	62.8	57.8	61.3	57.0
Days 31–60	52.8	44.5	49.2	44.2
Days 61–90	45.6	42.9	42.2	31.1
Weeks 1–12	53.8	52.8	52.3	47.6
Weeks 13–24	59.4	47.3	46.2	36.5
Weeks 1–24	56.6	49.7	50.1	44.3
Mean daily minutes engaged (over all days in the respective time period)				
Days 1–7	12.0	11.5	14.4	6.2
Days 1–30	5.5	6.9	11.9	4.2
Days 31–60	1.0	4.5	7.2	3.3

Days 61–90	2.0	3.0	6.2	2.4
Weeks 1–12	2.8	5.0	8.7	3.5
Weeks 13–24	1.9	3.0	7.0	2.5
Weeks 1–24	2.4	4.1	7.9	3.1

CAT = COPD Assessment Test; EMM = electronic medication monitor; PH = Propeller Health.

Supplementary Table 5. Adherence to ELLIPTA inhaler delivered maintenance medication use by baseline CAT score

	As-prescribed medication use, days (%)			
CAT score	**<10**	**11–20**	**21–30**	**>30**
n	6	47	61	17
Days 1–7	90.48	74.16	68.48	67.23
Days 1–30	95.56	82.46	76.93	71.24
Days 31–60	93.89	88.06	77.18	74.10
Days 61–90	89.44	84.42	74.66	79.47
Weeks 1–12	92.46	85.03	76.62	73.04
Weeks 13–24	95.47	77.25	65.77	59.39
Weeks 1–24	93.90	81.83	72.88	68.56

CAT = COPD Assessment Test.

Reference

1. Global Initiative for Chronic Obstructive Lung Disease (GOLD). *Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease (2021 report).* 2021.