Conclusions The EMSCI is a reliable and valid instrument that was developed based on patients' experiences to evaluate early morning symptoms and impacts of COPD. It is available to be used for clinical decision making and as a clinical study endpoint for the evaluation of new treatments.

Abstract P218 Table 1 Correlation¹ of EMSCI Domain Scores with SGRQ, E-RS Total and FEV₁²

	Six-item Symptom Summary Score ³	Overall Early Morning Symptoms Severity ⁴	Activity Limitation	Early Morning Puffs of Rescue Medication
SGRQ	0.59***	0.56***	0.64***	0.33***
total score SGRQ symptoms	0.67***	0.58***	0.52***	0.33***
score SGRQ impacts	0.54***	0.52***	0.60***	0.32***
score E-RS total score	0.83***	0.80***	0.73***	0.35***
	04	10	13**	13

¹ Spearman rank order correlation coefficients: ***P<0.0001, **P<0.001, *P<0.05

P219 EVALUATION OF INDIVIDUAL ACTIVITY DESCRIPTORS OF THE MRC DYSPNOEA SCALE: DO THEY ADD UP?

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Introduction The MRC dyspnoea scale consists of five grades that contain of a description of more than one activity. The comparability of these components is not known. This study aimed to examine the performance of individual descriptions of each MRC grade.

Methods Phase I: cognitive debriefing with COPD patients was conducted to elicit their understanding of each activity (10 items) of the five MRC grades. Phase II: COPD patients completed the MRC scale (grades 1–4) and a MRC-Exploded (MRC-Ex) version consisting of 10-items, each representing one MRC activity. Each item used a 4-point response scale (0 'not at all' to 4 'all of the time'). Rasch analysis was used to assess the pattern of MRC-Ex item severity (logit) to assess the appropriateness of combining individual activity descriptors into single MRC grades.

Results 36 patients participated in cognitive debriefing. Key issues identified: MRC 1: unclear what constituted 'strenuous exercise' and does not represent mild severity and MRC 5: 'too breathless to leave the house' viewed as "much worse than being breathless with dressing". 203 patients completed Phase II (mean age 64.7 SD 7.5 years, GOLD: 1:14% 2:41% 3:25% 4:7%). The easiest item to affirm was 'walking up a slight hill' (logit –2.76) and "too breathless to leave the house" was the most difficult (logit 3.42) (Table 1). MRC components in grade 5 are not of equivalent severity - at least 2 logits apart.

Conclusions This study highlight the importance of context when using the MRC. Grade 1 "strenuous exercise" is unlikely to yield a reliable response from patients diagnosed with COPD. Secondly, if data collection is taking place outside of the home then it is pointless to ask respondents if they are too breathless to leave the house; on the other hand, if studying patients who may require palliative care services, that might well be relevant. For contexts where it would be relevant, we suggest separating Grade 5 components: "leave the house" and "dressing/undressing".

MRC Grade	Item	Severity (logit
2	slight hill	-2.76
2	Hurrying on flat	-2.519
1	Strenuous exercise	-1.389
3	same age	-0.847
3	own pace	0.043
4	100metres	0.427
4	few minutes	1.051
5	dressing	1.1
5	undressing	1.472
5	leave house	3.422

P220 DETERMINANTS OF INHALER ADHERENCE IN A COPD POPULATION

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Introduction Inhaler adherence in Chronic Obstructive Pulmonary Disease (COPD) is a crucial component of disease management with studies reporting relationships with both morbidity and mortality. The aim of this study was to identify determinants of inhaler adherence.

Methods Over a 3-year period data was collected on 265 patients with COPD whose inhaler adherence was monitored for one month. Data on personal factors (i.e., cognition, anxiety and depression), disease severity and socioeconomic factors was collected. In addition, after one month of recruitment, information on exacerbations, re-admissions, quality of life, symptoms, self-reported adherence, beliefs in medicines and psychological status were collected. Inhaler adherence was calculated as a combination of timing of use, interval between doses and technique of use (Actual Adherence).

Results At one month, patients who reported worse breathlessness (5 on the MRC Dyspnoea Scale) had worse Actual Adherence (p = 0.03). Interestingly, patients who had an exacerbation of their COPD within the month after recruitment had significantly lower Actual Adherence than those that didn't (p = 0.01). In addition, patients with poorer cognition (p = 0.02), poorer cough PEFR (p < 0.01) and more severe COPD (GOLD Stage IV, p = 0.05) had worse Actual Adherence.

Conclusion In the large observational study of severe COPD patients, poor inhaler adherence was associated with worse symptoms, poorer cognition, more severe COPD and more exacerbations. This has significant implications for the long-term

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² Morning pre-dose value

³ Average score of six symptoms (Cough, Wheezing, Shortness of breath, Tightness in your chest Chest congestion, Difficulty bringing up phlagm)

chest, Chest congestion, Difficulty bringing up phlegm) ⁴ Single-item measuring overall early morning COPD symptom severity

E-RS = Evaluating Respiratory Symptoms in COPD; FEV_1 = forced expiratory volume in 1 second; SGRQ = St. George's Respiratory Questionnaire

treatment of this patient population and may guide future interventions.

P221

COMPARING THE PERCEPTION OF FEED-BACK MECHANISM OF THE BREEZHALER® DEVICE WITH THE ELLIPTA® DEVICE IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD): THE ADVANTAGE STUDY

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Background and aims Patient preference and satisfaction with inhalers are important factors that may impact adherence to treatment and hence its outcome. The ADVANTAGE study compared the Breezhaler and the Ellipta inhalers for patient perception of feedback mechanism and the comfort of the mouth piece, in COPD patients, naïve to dry powder inhaler use.

Methods This open-label cross-over study randomised (1:1) patients (\geq 40 years) with COPD [all severities as per GOLD 2014] and smoking history of \geq 10 pack-years to use both the Breezhaler[®] and Ellipta[®] devices in differing sequences with a separation of \geq 5 minutes between devices. After inhalation, patients completed a questionnaire² containing 4 questions that captured patients' perception of the feedback mechanism (mean of first three questions) and comfort of the mouth piece (fourth question). Questions were answered on a scale of 1 (lower preference) to 5 (higher preference), a Wilcoxon signed rank test was performed to test the difference between devices at a 2-sided 2.5% level of significance for both endpoints. Safety assessments

included adverse events, physical examination, vital signs, height and weight.

Results One hundred patients (64 men and 36 women) with a mean (SD) age of 65.2 (9.07) years were randomised to inhale sequentially through both devices. Thirty two patients were current smokers and had a mean (SD) duration of COPD for 6.1 (4.82) years. Overall, patients perceived that the Breezhaler inhaler offered greater confidence of dose delivery and better comfort of the mouth piece (mean (SD) score 4.3 (0.70) and 4.3 (0.82); respectively) vs. the Ellipta inhaler [mean (SD) score 3.6 (1.05) and 3.9 (0.84); respectively] (Figure). No safety signals were identified during the study.

Conclusions In this study, COPD patients had greater confidence of receiving full dose with the Breezhaler® device and better comfort with the mouth piece compared with the Ellipta® device.

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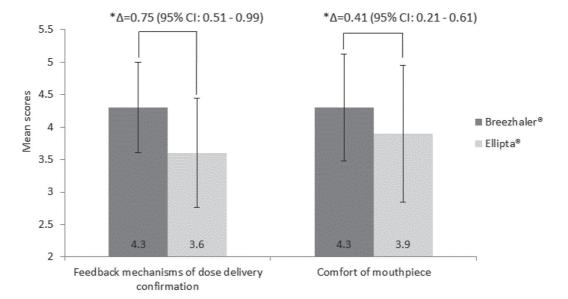
P222

INPUT OF A PATIENT ADVISORY GROUP INTO
EVALUATING THE BENEFIT: RISK PROFILE OF EXISTING
AND POTENTIAL COPD THERAPIES

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Introduction People with chronic obstructive pulmonary disease (COPD) have considerable disability and reduced life expectancy, despite current treatments. New medicines are required, but few successfully complete clinical trials and become established in practice. During drug development, understanding the nature and magnitude of benefits relevant to patients and risks they will accept to achieve these is important, particularly where the drug has a narrow therapeutic index. Our aim was to explore patient



Data are presented as mean (standard deviation); Δ, treatment difference; CI, confidence interval

* p<.0001

Abstract P221 Figure 1 Mean Scores of the analysis of patients preference of the Breezhaler and the Ellipta devices

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