OBJECTIVES: To develop a self-administered patient reported outcome (PRO) instrument to evaluate patients' experience of early morning symptoms of Chronic Obstructive Pulmonary Disease (COPD). **METHODS:** A literature review and interviews with six clinical experts were performed to identify concepts for the evaluation of early morning symptoms of COPD and to develop a focus group discussion guide. Four focus groups were conducted with a total of 27 COPD patients who experienced COPD symptoms at night or in the early morning. Qualitative data was analyzed using ATLAS.ti to identify key concepts and patient terminology which were then used to create a conceptual framework and to generate items and response options for the new PRO instrument. One-on-one cognitive debriefing interviews were conducted with 10 COPD patients to assess item readability, comprehensiveness, and content validity. **RESULTS:** Focus group participants had a mean age of 68.1 years, were 51.9% female, and had a range of COPD severity levels: 7.4% GOLD I (mild), 55.6% GOLD II (moderate), 14.8% GOLD III (severe), 22.2% GOLD IV (very severe). Most of the participants experienced COPD symptoms in the early morning (n=25, 92.6%). Patients noted symptoms such as cough and impacts such as restricted morning activities. Cognitive debriefing interviews demonstrated that the items were comprehensive, relevant and interpreted as intended. A few items were edited to improve clarity based on feedback from the patients. **CONCLUSIONS:** The Early Morning Symptoms of COPD Instrument (EMSCI) is a PRO instrument developed to evaluate the full range of early morning symptoms of COPD. The instrument was developed based on patients' experiences to support content validity. The EMSCI can be used to characterize COPD patients' experience of early morning symptoms for clinical decision making and for the evaluation of new treatments.

PRS52

INPATIENT HOSPITAL CARE OR HOSPITAL-AT-HOME FOR COPD EXACERBATIONS: A DISCRETE CHOICE EXPERIMENT

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OBJECTIVES: Hospital-at-home programs for COPD exacerbations aim to provide care efficiently by shortening or avoiding hospital admissions. The objective was to quantify Dutch patient and informal caregiver preferences for different aspects of hospital-at-home. **METHODS:** In a discrete-choice experiment, respondents made 14 choices between regular hospital admission (7 days) and two programs in which 3 hospital days were followed by a 4-day treatment at home. The home treatment was described by a set of attributes (see results). Hospital treatment was constant across choice sets. Respondents were patients and their informal care givers who participated in an RCT on the cost-effectiveness of hospital-at-home versus regular hospital care. The data were analyzed in latent-class conditional logit models, which allowed for heterogeneity across groups. **RESULTS:** A total of 202 questionnaires were returned. 25% of patients and caregivers always opted for hospital treatment, 46% always chose hospital-at-home. For both groups, the best fit was provided by a model with four latent classes, depending on preference for hospital and caregiver burden. All attributes had the expected sign and a significant effect on choices, except for number of home visits. Attribute levels with the strongest impact were hospital preference (for patients, coefficients (depending on class): -5.62 to +3.3), a 5h/day caregiver burden (-3.5 to -0.11) and co-payment of €100 (1.11). Also influential were specialized training for the homecare nurse (0.52), visits by many different nurses (-0.43), high readmission risk (-0.41), GP instead of hospital as contact for emergencies (-0.63), €50 co-payment (-0.48), 3h/day caregiver burden (-0.32), medium readmission risk (-0.24). Results were similar for informal care givers. **CONCLUSIONS:** A considerable proportion of patients and caregivers have a fixed preference for either admission or hospital-at-home, regardless of the specifics of the program. When choosing between hospital-at home programs, co-payments and the burden on informal caregivers are the principal attributes.

PRS53

FURTHER DEVELOPMENTS OF THE ASTHMA LIFE IMPACT SCALE (ALIS)

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OBJECTIVES: The Asthma Life Impact Scale (ALIS) is a disease-specific measure used to assess the quality of life of people with Asthma. It was developed in parallel in the UK and US and has proven to be acceptable to patients, to have good psychometric properties and to be unidimensional. The objective of this study was to adapt and validate the ALIS for use in Italy and Russia. **METHODS:** The dual panel methodology was used to translate the ALIS for both cultures. Patient interviews were conducted to test the new language versions to ensure their face and content validity. A test-retest postal survey was conducted in both countries to assess the psychometric properties of the new adaptations. **RESULTS:** The translation process proved straightforward. Cognitive debriefing interviews conducted in Italy (n=15) and Russia (n=9) indicated that patients found the new versions of the ALIS easy to complete and relevant. Validation data were available from postal surveys in Italy (n=61) and Russia (n=71). Both new versions of the ALIS had good internal consistency (0.92) and high test-retest correlation coefficients (Italian = 0.86; Russian = 0.94) indicating good reproducibility. The Russian ALIS showed strong correlations with a measure of fatigue (CAFS; 0.87) and sleep (CASIS; 0.85). The Italian ALIS had a moderate correlation with the Nottingham Health Profile Energy level scale (0.63). Both adaptations of the ALIS were able to distinguish between patients based on their self-rated general health and asthma severity. **CONCLUSIONS:** The ALIS was successfully adapted for use in Italy and Russia. The psychometric properties of these new adaptations matched those of the original UK and US versions. The new instruments represent valid and reliable tools for measuring QoL in international clinical trials and for use in routine clinical practice.

PRS54

TESTING OF A CONCEPTUAL MODEL OF ASTHMA IN ADOLESCENTS

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OBJECTIVES: Conceptual Models (CM) are useful for characterising domains of Symptoms, Functioning and Treatment Satisfaction. Previously a Conceptual Model (CM) of asthma was developed and relevance to patients confirmed through qualitative interviews with 15 asthmatic adults. The aim of this research was to test the model in adolescents. **METHODS:** Twenty semi-structured interviews were conducted with asthmatic adolescents (aged 12-16) in the US. Cards were used to elicit feedback from the patients on their understanding and experience of different concepts included in the CM (symptoms and functioning/disability). Patients used the cards to rank the importance of symptoms and impacts. Treatment satisfaction was also discussed and the Asthma Control Test (ACT) completed. **RESULTS:** Based on the ACT 40% (8/20) of adolescents had poorly controlled asthma compared with 13% (2/15) of adults in the previous study. Most adolescents reported experiencing all four core symptoms of asthma; breathlessness (n=20), tight chest (n=19), cough (n=18) and wheeze (n=20). Additional symptoms reported by the adolescents were light-headedness (n=7), shaking (n=6), congestion (n=5), feeling as if about to pass out (n=2), vomiting (n=2) and an uncomfortable feeling in the ribcage (n=2). Breathlessness was the most important and bothersome symptom for both adolescents and adults. The functioning/disability concepts relevant to adolescents were the same as for adults. 'Spending time with friends/family' was the impact ranked as most important by adolescents (n=5). Understanding of terms and definitions was good for all core symptoms and impacts. The term 'rescue inhaler' was not familiar to a minority (3/12, 25%) of younger adolescents. **CONCLUSIONS:** Qualitative analysis of the interviews found evidence supporting all concepts in the CM. New symptoms reported by adolescents were distal symptoms experienced due to poorly controlled asthma or rescue medication overuse. No changes to the CM for asthma are needed for adolescents.

PRS55

FURTHER DEVELOPMENTS OF THE LIVING WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (LCOPD)

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OBJECTIVES: The Living with Chronic Obstructive Pulmonary Disease (LCOPD) scale is a disease-specific measure used to assess quality of life of people with COPD. The measure was developed in parallel in the UK and US and was shown to be highly acceptable to patients, unidimensional and have very good psychometric properties. The objective of this study was to adapt and validate the LCOPD for use in Italy, Spain and Russia. **METHODS:** Translated versions were produced using dual panel methodology. The translated versions were tested with patients to ensure face and content validity. Test-retest postal surveys were conducted to establish internal consistency, reproducibility and construct validity. **RESULTS:** The translation process proved successful for the new language versions. Cognitive debriefing interviews conducted in Italy (n=15), Spain (n=14) and Russia (n=8) indicated that patients found the new versions of the LCOPD acceptable and easy to comprehend. Validation data was generated from postal surveys in Italy (n=51), Spain (n=142) and Russia (n=69). All three versions showed good internal consistency ranging from 0.94-0.95, and good reproducibility was evident from the high test-retest correlation scores (Italian=0.96, Russian=0.94, Spanish=0.85). The Russian LCOPD had strong correlations with a measure of fatigue (CAFS; 0.87) and sleep (CASIS; 0.76). The Spanish LCOPD had a moderate correlation with the CAFS (0.66) and a strong correlation with the CASIS (0.75). The Italian LCOPD had strong correlations with three of the sub-scales of the Nottingham Health Profile (0.83) and with the NHP-D (0.86). The new adaptations of the LCOPD were all able to distinguish between patients based on their self-rated general health and COPD severity. **CONCLUSIONS:** The LCOPD was successfully adapted for use in Italy, Spain and Russia. These results were similar to those found for the original UK and US versions.

PRS56

ASSESSING PATIENT REPORT OF FUNCTION: CONTENT VALIDITY OF THE FUNCTIONAL PERFORMANCE INVENTORY-SHORT FORM (FPI-SF) IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

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OBJECTIVES: The performance of daily activities is a major challenge for people with chronic obstructive pulmonary disease (COPD). The 65-item Functional Performance Inventory (FPI) was developed to quantify these difficulties in naturalistic studies and clinical trials. The instrument was based on an analytical framework of functional status and qualitative interviews; it was reduced to a 32-item short form (FPI-SF) through a systematic process of item reduction and testing and re-formatted for greater clarity and ease of use. This study assessed the content validity of the FPI-SF. **METHODS:** Qualitative cognitive interviews were performed with men and women with COPD recruited through pulmonary clinics in the United States. Interviews were conducted in-person by a trained interviewer using a semi-structured interview guide and continued to saturation. Qualitative data analyses included the following: 1) comprehensiveness; 2) clarity of instructions, items, and response options; 3) respondent interpretation of the instructions, items, and re-