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 identified factors which contributed to early morning symptoms ranging from 0.94-0.95, and good reproducibility was evident from the high test-retest correlation of 0.94-0.95, and good 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 interpret. 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

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

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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 the functional status and disability in people with COPD. The purpose of this study was to assess 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 response options; and 4) 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 in the MM. CONCLUSIONS: 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 being late for school (n = 17) or missing activities (n = 18) ‘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: The MMF of the ALIS of asthma was developed and relevant to patients confirmed through qualitative interviews with 15 asthmatic adults. The instrument was developed based on patients’ experiences to support content validity. The ESMCI 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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OBJECTIVE: To compare the efficiency of hospital care versus hospital-at-home for patients with COPD exacerbations. METHODS: In a discrete-choice experiment, respondents made 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 4 focus groups. Results were comparable for the cost-effectiveness of hospital-at-home versus 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): −0.62 to +3.3, a shorter hospital stay (−0.28 to +0.85) and hospital-at-home preferred (0.11). Also influential was 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, Spain and Russia. 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 being late for school (n = 17) or missing activities (n = 18) ‘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: The MMF of the ALIS of asthma was developed and relevant to patients confirmed through qualitative interviews with 15 asthmatic adults. The instrument was developed based on patients’ experiences to support content validity. The ESMCI can be used to characterize COPD patients’ experience of early morning symptoms for clinical decision making and for the evaluation of new treatments.

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

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OBJECTIVE: 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 complete. The correlation of validation data 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 (CABS, 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 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.