A375

one study. **CONCLUSIONS:** Our review showed that PROs are often included in COPD product labels in Europe and in the USA. Although the FDA and the EMA agree on a general level, the FDA seems more restrictive in the label wording.

PRS50

STUDY OF QUALITY OF LIFE IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) AND SYMPTOM ASSESSMENT DIFFERENCES BETWEEN PATIENTS AND FAMILY MEMBERS

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OBJECTIVES: To assess the relationship between the questionary of quality of life "COPD assessment test" (CAT) and clinical, functional and comorbidity parameters and compare patient perceptions of symptoms with that of their family members. METHODS: We analysed demographic (age, sex, BMI), lung function (FEV1%) and comorbidity variables (Charlson index) in patients with stable COPD. Patients and family members independently completed the CAT (family members reported their observations of the patient). RESULTS: We included 70 patients (83% men, mean age 72±9.4 years, BMI 27.8±4.2 kg/m², Charlson index (ChI) 2.41±1.7, mean FEV $_1\%$ 57.1±15.1%. Air flow limitation (GOLD): 7 patients (9%) mild, 36 (53%) moderate, 24 (34%) severe and 3 (4%) very severe. There was a significant negative correlation between CAT and FEV $_{1\%}$ (r=-0.265, p<0.0028) but no correlation between CAT and ChI, age or BMI. A comparison of CAT scores between the patients and their family members showed that 61% of the patients underestimated and 33% overestimated their symptoms (CAT scores: 15.5±7.9 (patient) vs. 17.1±7.7 (family) (p<0.038); correlation: (r=0.72; p<0.001). We observed correlations in the 8 CAT items. We found significant differences between the patients and their family members in items 1: coughing (p<0.015), 3: chest tightness (p<0.005) and 6: confidence leavin forms (p<0.015) and in overall score (p<0.038). **CONCLUSIONS:** 1. We found a negative correlation between the CAT and FEV₁but not between the CAT and Charlson index. 2. Patients underestimate their symptoms. Cough, chest tightness and confidence leaving home are the issues items that had the greatest discrepancy between patients and family members.

PRS51

COMPARISON OF TREATMENT SATISFACTION IN PATIENTS WITH ASTHMA TAKING LEUKOTRIENE MODIFIERS VERUS THOSE TAKING INHALED CORTICOSTEROIDS

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OBJECTIVES: To assess treatment satisfaction between patients with self-reported asthma for two classes of asthma treatments, leukotriene modifiers (LM group) and inhaled corticosteroids (IC group), using a novel patient community in the U.S. **METHODS:** Participants were identified via MediGuard, a digital patient platform where patients enroll online to be part of a digital patient community. All information was obtained through participant self-report. Patients were invited to complete the Treatment Satisfaction Questionnaire for Medication (TSQM), a patient reported outcome (PRO) instrument, at random time points between 2009 and 2011. Domain scores of the TSQM were compared between the IC and LM groups using regression analyses, adjusting for age, gender, self-reported severity and number of co-medications. **RESULTS:** A total of 736 patients were included for the IC group, and 647 for LM group. Average ages were comparable (56.3 years (SD=13.8) for IC; 54.9 (13.5) for LM). Both groups were predominantly female (76.3% IC; 83.2%, LM). Effectiveness domain scores were similar between IC and LM groups (p=0.502). LM users reported significantly higher scores (i.e., increased satisfaction) for other domains: side effects (97.1 (SD=0.8) vs. 93.5 (0.7), resp.); convenience (89.2 (0.8) vs. 81.6 (0.7), resp.); global satisfaction (72.3 (1.1) vs. 67.3 (1.0). CONCLUSIONS: Patients in the LM group reported higher satisfaction in the convenience and global satisfaction domains than the IC group. Patients in the LM group reported less interference with side effects than the IC group. Providing patients with information on population-based satisfaction scores for these two medications could help inform patients' treatment selection decisions.

PRS52

SYMPTOMS OF COPD IN URBAN RUSSIA AMONG ADULTS 40 YEARS AND OLDER $\underline{Vietri}\, J^1,$ Ertl $S^2,$ Isherwood $G^3,$ Bevelskiy AS^4

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OBJECTIVES: Chronic obstructive pulmonary disease (COPD) is a major cause of disability worldwide, but awareness of COPD and information regarding the burden of this disease are lacking worldwide, including Russia. The aim of the current study was to assess the prevalence of COPD symptoms (cough with mucous, wheezing, and shortness of breath) among a representative sample of adults aged 40 and above in major cities in Russia. METHODS: Data was obtained from the 2011 Russia National Health and Wellness Survey, a cross-sectional survey of the adult population in the city adult population in Russia which includes information on awareness, experience, and diagnosis of medical conditions, health care-related attitudes, demographic characteristics, and health outcomes. The frequency of COPD symptoms was assessed using the Lung Function Questionnaire, and health status was assessed using the SF-12v2. Those experiencing a symptom at least 'sometimes' were compared to those who experienced the symptom 'rarely' or less using independent-samples t-tests. RESULTS: A total of 5920 adults aged 40 and older completed the survey. After weighting, 45%, 27%, and 18% reported shortness of breath, coughing up mucous, and wheezing, respectively, and 54% reported at least one symptom. Only 23% of those surveyed were aware of COPD; awareness of COPD was greatest among those with the most symptoms but even among those with all three symptoms, only 31% were aware of the condition. Experience of each symptom was associated with worse mental and physical component summary scores on the SF-12v2, with decrements ranging from 2-6 points depending on the symptom and score considered. CONCLUSIONS: Respiratory symptoms are common among adults living in Russian cities, which may indicate high COPD incidence. Awareness of COPD in Russia is lacking. A high proportion of adults aged 40 and older in Russia report frequent respiratory symptoms, and these symptoms are associated with significantly worse health status.

PRS53

THE RELATIONSHIP BETWEEN COPD ASSESSMENT TEST (CAT) AND EQ-5D IN A REAL WORLD PATIENT POPULATION

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OBJECTIVES: COPD is a chronic lung disease that has a detrimental effect upon patient's quality of life. The COPD Assessment Tool (CAT) has been developed to measure the impact of the disease. This research explores the relationship between the disease-specific CAT, and the general health related utility measure EQ-5D. METHODS: COPD is a chronic lung disease that has a detrimental effect upon patient's quality of life. The COPD Assessment Tool (CAT) has been developed to measure the impact of the disease. This research explores the relationship between the disease-specific CAT, and the general health related utility meas-ure EQ-5D. **RESULTS:** A scatter plot relating CAT score to EQ-5D showed that the relationship is non-linear. Variance of the EQ-5D score increased with CAT score, suggesting the increasing influence of confounding factors for patients reporting a higher CAT score (CAT score range variance: 0-10: 0.013, 11-20: 0.026, 21-30: 0.050 and 31-40: 0.126). A generalized linear model was used to account for the non-linear relationship, and control for confounding influences of age, gender, physician-perceived COPD severity and number of concomitant conditions, with no assumption of constant variance. The relationship between CAT and reversed EQ-SD was positive and significant (conficient 0.070, p-value < 0.0001), illustrating higher CAT score was associated with lower EQ-SD. A one point increase in CAT score resulted in an approximate 7.2% relative decrease in EQ-5D score. Similarly, significant (p-value <0.0001) negative relationships observed for older patients (coefficient 0.016), female gender (coefficient 0.147), greater severity (coefficient 0.469), and a higher number of comorbidities (coefficient 0.070). CONCLUSIONS: Increasing COPD impact as measured by the CAT was associated with lower EQ-5D scores. However, the increasing variance of EQ-5D for patients with higher CAT scores demonstrates the need for both COPD impact and overall health status assessment.

PRS54

THE RELATIONSHIP BETWEEN ASTHMA-SPECIFIC QUALITY OF LIFE AND MEASURES OF ASTHMA CONTROL AND GENERIC QUALITY OF LIFE Study \mathbb{R}^1 Subdours of C Fadeward NC F between \mathbb{R}^2

 $\frac{Stucky\,B^1}{RAND} Corporation, Santa Monica, CA, USA, ^2The RAND Corporation, Santa Monica, CA, USA, ^2THE MON COR$ **OBJECTIVES:** Previous research has indicated a strong relationship between asthma symptoms and asthma-specific quality of life (QoL). However, past measures of asthma-specific QoL typically confound symptoms and functional impairment with QoL, which in turn may cause a misleadingly high inter-correlation. The current research uses a newly developed measure of asthma-specific QoL (the RAND-Impact of Asthma on Quality of Life; RAND-IAQL) that controls for asthma symptoms and functional impairment while assessing the degree of asthma impact or burden. Using this new measure, we model the relationship between asthma specific quality of life, generic quality of life, asthma control, and comorbid conditions commonly associated with asthma. METHODS: Using a diverse sample of adults with asthma (N=2032), we use structural equation models (SEM) to establish the relationships and suppression effects of asthma control, symptoms, comorbidities (e.g., COPD, Sinusitis), and multiple PROMIS QoL instruments (including anxiety and social QoL) on the prediction of asthmaspecific QoL. SEM models will be presented sequentially in order to evaluate the relative utility of increasingly complex models using likelihood ratio tests and changes in the amount of IAQL variance that is accounted for by each added predictor (latent) variable. **RESULTS:** Close fitting SEM models suggest that interference" caused by asthma, an indicator commonly used to measure asthma control, is most strongly related to asthma-specific QoL. Contrary to the research literature, symptoms of asthma (including shortness of breath, wheezing, and cough) and comorbid diseases are less strongly related to asthma specific QoL than are general assessments of interference and generic measures of anxiety and limitations in social functioning. **CONCLUSIONS:** Asthma-specific QoL is best understood as the degree to which asthma impacts or burdens ones daily life. While asthma symptoms, control, and general QoL are highly inter-correlated, asthma control (primarily interference) is differentially predictive of asthmaspecific OoL.

PRS55

THE RAND NEGATIVE IMPACT OF ASTHMA ON QUALITY OF LIFE ITEM BANK AND SHORT-FORMS

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OBJECTIVES: In response to recommendations from the 2010 NHLBI Asthma Outcomes Workshop, we developed a new system for measuring the impact of asthma on quality of life (QoL) that avoids confounding QoL with asthma symptomatology and functional impairment. This presentation summarizes the process of developing and validating an item bank and short-forms that measure patients' perceptions of the impact or bother of asthma on their life. **METHODS**: Focus groups, supplemented by literature review and expert panel recommendations were used to identify key QoL dimensions and develop a pool of items which were refined based on cognitive interviews. Items were field-tested using a diverse national sample of adults with asthma (N=2032). Modern measurement theory was used to develop an item bank and short forms. We validated our short-forms against the Marks AQLQ; ACT; and generic QoL measures. Discriminant validity was examined by evaluating scores from respondents who differed according