ods (76.7%), inhaled-anticholinergic (70.7%), mucolytics (19.4%), xanthine (7.3%), oral-corticosteroids (1.3%). BDI grade 2 primary outcome: RCT cohorts: there was no difference between control and intervention A and there were statistically significant differences between intervention B versus control (p<0.001), NNT=3.22 (IC95%, 2.27-5.88) and versus intervention A, NNT=4.16 (IC95%, 2.63-10). In the FFS cohort: performance of (p<0.001) intervention B versus intervention A, equivalence NNT=3.22 (IC95%, 2.32-5.55). The preferences enhanced a 6.7% the correct inhalation conclusion.

CONCLUSIONS: The performance of a correct inhalation technique improves with monitor training. The patients’ preferences enhance the efficacy of intervention.

PR568
INHALATION TECHNIQUE EVOLUTION AFTER TRAINING IN COPD. THE ROLE OF THE DEVICE
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OBJECTIVES: To test the efficacy of two educational interventions to improve the inhalation techniques per device in patients with COPD and the influence of patient preference. METHODS: Design: Multicenter patients’ preference trial or comprehensive cohort design SIRCTN15162264. Patients: 465 COPD patients (to detect a difference between groups of 25%, 80% statistical power, 95% confidence level, 40% expected losses), with inhaled treatment, written consent. Non-probabilistic consecutive sampling. Allocation: Patients without strong preferences for a treatment are randomized. RCT group (Block randomization), and those with strong preferences are assigned their choice: PPS group. Variables: Performance of inhalation technique; Interv-A: A leaflet with inhalation technique, Interv-B: Interv-A + a individual training (by instructors). Follow-up: 3 months, visits: baseline (V0), 1 month (V1), 3 month (V2). Statistical analysis: Mean, frequency, 95% confidence interval. Intention to treat analysis. Results: A total of 160 patients were included (Male 91.4%, mean age 68 ± 9 years (IC95%, 62.8-68.4), FEV1 (mean)=55.91% (IC95%, 53.62-58.2), mixed respiratory pattern (65.9%). Severity stage: 15.7% mild, 44.1% Moderate, 40.3% Severe. BDI: grade 2. Devices use: 67.3% Handihaler (HD), 54.8% Turbuhaler (Th), 31.8% Accuhaler (Acc), 26.9% pMDI. Correct Inhalation technique: Interv-B: control 11.7% V0,10% (V2); Intervention-A 10.9%, 17.5%; Intervention-B 10.9%, 17.5%; Intervention-A 7.4%, 32.6% p<0.001. Th: control: 22% V0, 16.7% (V2); Intervention-A: 8.7%, 24.4%; Intervention-B: 7.5 %, 57.5% p<0.001. Acc: control: 16.1% V0, 25% (V2); Intervention-A: 17.9%, 23.1%; Intervention-B: 11.5%, 74.1% p<0.001. pMDI: control 6.9% V0, 3.6% (V2); Intervention-A: 12.5%, 19%; Intervention-B: 8.3%, 34.6% p<0.025. There were statistically differences for all devices only in the intervention B arms (p<0.001). The preferences enhanced 1% for Handihaler, 12.7% for Accuhaler, 4.6% for Turbuhaler, 15.4% for pMDI the correct inhalation technique. CONCLUSIONS: The performance of a correct inhalation technique improves with monitor training for all devices. The patients’ preferences enhance the efficacy.

PR569
IDENTIFICATION OF DRY POWDER INHALER ATTRIBUTES AND THEIR RELATIONSHIP TO ASTHMA AND CHRONIC OBSTRUCTIVE PULMONARY DISEASE PATIENTS’ CHOICE: TO INFORM A DISCRETE CHOICE EXPERIMENT
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OBJECTIVES: To identify characteristics of dry powder inhalers (DPIs) considered important by asthma and chronic obstructive pulmonary disease (COPD) patients, in order to develop attributes and attribute levels for a discrete choice experiment. METHODS: Qualitative data was collected from a literature review performed to determine which inhaler attributes impact inhaler satisfaction and adherence among asthma and COPD patients using DPIs. Focus groups with asthma and COPD patients were formed during the translation process. It is unclear whether this additional step in instrument development, in the language versioning process, was needed. Harmonization was performed to ensure conceptual equivalence of the NiSCI and EMSCI is typically conducted during instrument development, in the language versioning process, was needed. Harmonization was performed to ensure conceptual equivalence of the NiSCI and EMSCI for use in 14 countries. Austria, Bulgaria, Canada, Czech Republic, France, Germany, Hungary, Italy, Lithuania, The Netherlands, Poland, South Africa, Spain, and United Kingdom. METHODS: The NiSCI and EMSCI were translated following ISPOR guidelines for linguistic validation of PRO measures Wild et al., 2005 using the universal approach discussed in the second task force report (Wild et al., 2009). The universal English, Spanish and French versions were previously translated (Eremenco et al., 2012). For the remaining languages, two forward translations by native translators, reconciliation of the forwards, one back-translation by an English speaker fluent in the target language, and a consensus meeting by a native speaker were conducted for both measures. Harmonization was performed to ensure conceptual equivalence across languages. Interviews were conducted with five native-speaking COPD patients per language to examine importance. Interviews were analyzed to assess linguistic and cultural validity in each language and confirm conceptual equivalence. RESULTS: Mean age of the sample (N=80) was 60 years (range 41-83) and 54% were male. The translations were well understood and considered relevant, with one exception: expressing only dyspnea burden, which was translated to the universal French (chest congestion), Hungarian (wheezing, chest congestion), Italian (chest congestion, moderately), and Lithuanian (instructions, wheezing, shortness of breath, experienced) following the patient interviews. CONCLUSIONS: All translated versions of the NiSCI and EMSCI in this study were found to be conceptually equivalent and acceptable for use in the 14 evaluated countries.

PR572
TESTING E-PRO DEVICE USBABILITY DURING THE TRANSLATION PROCESS: A CASE STUDY OF THE EXACT IN 7 COUNTRIES
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OBJECTIVES: Usability testing of electronic Patient-Reported Outcomes (ePRO) instruments is typically conducted during instrument development, in the language/country of origin. It has been suggested that usability testing also be performed during the translation process. It is unclear whether this additional step is necessary. In this study, usability testing was conducted as part of the linguistic validation process in each country. The French, Dutch (France), Russian (Russia), and Spanish (Universal, tested in Chile, Spain, and US) for the Exacerbations of Chronic obstructive pulmonary disease tool (EXACT), an e-PRO tool developed and tested in the US. The translation process followed ISPOR guidelines (Wild et al., 2005). Cognitive interviews were conducted with 2-3 native-speaking COPD respondents per language/country combination in 2008. Subjects completed the exact in paper-pen screenshot format and were interviewed about their translation experience. Subsequently their responses were used to help create a FDA (Tungsten E2; CRF, Inc.) to complete the first 5 exact items and were interviewed regarding device usability. Interviewers rated subjects’ ability to use the device. RESULTS: Subjects (N=20) were 45-84 years, 60% male and 60% with secondary education or less. Most (n=18) had not used a FDA previously, all (n=20) reported
Idiopathic pulmonary fibrosis (IPF) is a progressive disease characterized by declining lung function, leading to debilitating limitations on activity.

**PRS73**

**A COMPARISON OF THE RELIABILITY AND VALIDITY OF THE FOUR-ITEM AND SIX-ITEM NISCI SYMPTOM SUMMARY SCORES**

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**OBJECTIVES:** The Nighttime Symptoms of COPD Instrument (NiSCI), developed through qualitative research with patients, includes six symptom items: coughing, wheezing, shortness of breath, difficulty bringing up phlegm, chest congestion, and pain in the chest. A symptom severity score is computed based on these items. In situations where patient burden is a major consideration, a smaller set of items may be preferable. Clinicians identified coughing, wheezing, shortness of breath, and difficulty bringing up phlegm as the most relevant for COPD patients. Exploratory psychometric analyses were conducted for the symptom summary score based on these four items compared with all six items.

**METHODS:** Psychometric properties of the four-item versus six-item symptom summary scores were reviewed and compared for their health impact in clinical trial data from a random split-half sample. NiSCI symptom summary scores were tested for: internal consistency using Cronbach’s Alpha; test-retest reliability using Intraclass Correlation Coefficients (ICC) and Concordance Correlation Coefficients (CC); convergent validity using Spearman’s Rank Order Correlation Coefficients; and known-groups validity using ANOVA and Scheffe’s test for pair-wise comparisons.

**RESULTS:** Patients (n=832) were aged 40-93 years (mean 63.78 ±9.07 [SD]) and 51% were male. Both scores were internally consistent and valid. Cronbach’s alpha was slightly higher for the six-item symptom summary (0.85) versus the four-item symptom summary (0.78). ICC and CCC scores were 0.85 for the six-item and 0.84 for the four-item symptom summary score, respectively. Both the convergent validity and other groups validity were similar for both scores (p>0.05).

**CONCLUSIONS:** The NiSCI symptom summary score based on four items has psychometric properties suitable for use in clinical trials. Further work will test the psychometric properties of the instrument administered with four items.

**PRS74**

**RELATIONSHIP OF QUALITY OF LIFE (HRQOL) IN PATIENTS WITH IDIOPATHIC PULMONARY FIBROSIS**

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**OBJECTIVES:** Idiopathic pulmonary fibrosis (IPF) is a progressive disease characterized by declining lung function, leading to debilitating limitations on activity.

**METHODS:** The study aimed to examine the association between key symptoms and HRQOL. METHODS: Individuals with IPF were recruited via patient advocacy organizations to complete an online survey consisting of PROMIS-29 health profile. The survey included a self-reported measure of physical and mental health, the Dyspnea Scale (MMRC), self-reported cough, and cough subscale of the ATAQ (A Tool to Assess Quality of life)-IPF. PROMIS-29 scores have mean 60.1; pain 62.6; dyspnea 65.2; depression 66.8; role-emotional 67; anxiety 68; pain 69; fatigue 71; social 72; role -usual activities 73. Dyspnea severity was associated with worse mean PROMIS-29 scores (all p<0.05).

**RESULTS:** The 275 survey participants showed worse mean PROMIS-29 scores than the general population in all measured domains (mean anxiety=63.9, depression=61.9, fatigue=60.1; pain=62.6; sleep disturbance=55.8; physical function=86.2; role-emotional=42.2). Dyspnea severity was associated with worse mean PROMIS-29 scores (all p<0.05). PROMIS-Dyspnes (mean=58.7) and Functional Limitations Due to Dyspnea (mean=58.4) were worse than the COPD reference population. Cough severity was associated with worse HRQOL measured by AT-AQ. Reliability of PROMIS-29 scores exceeded 0.65 and were moderately correlated with measures of similar constructs. A limitation of the study is that data drawn from a sample from advocacy organizations might not be generalizable to the entire IPF population. CONCLUSIONS: Patients with IPF report substantial deficits in HRQOL, particularly with respect to physical function, anxiety, pain, depression and fatigue. Patients suffering from dyspnea and cough had poorer HRQOL. These deficits should be monitored in clinical practice and evaluated in investigational trials aiming to improve the HRQOL of IPF patients.

**PRS75**

**ASTHMA AND COPD IN SPAIN: QUALITY OF LIFE AND HEALTH RESOURCES CONSUMPTION**

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**OBJECTIVES:** To analyze the impact that asthma and chronic obstructive pulmonary disease (COPD) have on patients Health Related Quality of Life (HRQOL) and on health resources consumed by the Spanish Health System. **METHODS:** Data obtained through the Health Information System of the National Health System in Spain (SERGAS) on asthma and COPD patients aged 18 years or older (n>150), identifying patients with a diagnosis of asthma or COPD. Descriptive statistic analysis was carried out, focused on self-reported HRQOL (EQ-SD), and resource utilization. The EQ-SD results were transliterated into QALYs, with the social tariffs validated in Spain. Other demographic factors, potentially related with the mentioned respiratory diseases prevalence, as age, smoking, habits were analyzed. Four groups were compared: 1) asthma patients; 2) COPD patients; 3) patients with other chronic conditions, and 4) global Spanish population. **RESULTS:** Data from 21,007 adults were recorded. Prevalence of asthma was slightly above COPD (5.4% vs 4.7%), and 47.2% were suffering from chronic obstructive pulmonary disease. Asthma patients suffer from more asthma-related ease-of-use findings in these diverse, device naïve subjects across 7 countries and the emphasis on subject training in clinical trials, it was determined that usability testing with future translations was unnecessary.

**PRS76**

**HEALTH RELATED QUALITY OF LIFE AMONG YOUNG SMOKERS**

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**OBJECTIVES:** As young students are more prone to smoking and associated dangers, the goal of this study was to assess the HRQoL and other associated factors affecting HRQoL among smokers and non-smokers who are students. **METHODS:** In this exploratory study a pilot research was conducted in different schools regarding young students. Demographics, BMI, food habits, alcohol consumption, family history of smoking as well as family history of diseases. For health related quality of life measurement both EQ-5D (US) and VAS (0=worst imaginable health state) were used. The data collected was analyzed using SPSS 16.0. The test of significance was done by using Chi square test for checking the associated habits and Mann Whitney U test is done to check the significance of association between HRQOL and smoking. **RESULTS:** Total 126 students were included in the study. The age was 22.9±2.17 (Mean±SD) and BMI was 22.03±4.7 (Mean±SD) and all of them were residing in an University town. 63 % of the students were non-vegetarians and 44.8% were consuming alcohol at least once in a month. The mean EQ 5D analogue score of the studied population was found to be 0.83±0.11 (Mean±SD). The Chi square test showed the association between smoking with family history of smoking, alcohol consumption and soft drink consumption (p<0.001 and 0.05 respectively). Mann Whitney U test showed as significant difference in the VAS scores among smokers and non-smokers (p<0.05).

**CONCLUSIONS:** Health Related Quality of Life is severely compromised by smoking, hence there is an urgent need to create awareness among young students.

**PRS77**

**HEALTH RELATED QUALITY OF LIFE AND HEALTH CARE UTILIZATION IN PRIMARY CARE PATIENTS WITH MODERATE/PERSISTENT SEVERE ASTHMA**

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**OBJECTIVES:** The aim of this study is to evaluate the health related quality of life (HRQOL) and health care utilization in primary care (PC) patients with asthma. **METHODS:** This is an observational study carried out in the primary health care of Asturias, Spain, and health care utilization from a cohort of 65 patients over 6 months. Inclusion criteria were patients aged 18 years and older with moderate/severe persistent asthma (GINA criteria) treated with beclomethasone/formoterol at least 1-3 months before the inclusion in the study. Sociodemographic variables such as age, sex, duration of disease, severity of asthma, concomitant pathology were evaluated. The evaluation of the HRQOL were measured with the Asthma Quality of Life Questionnaire (AQLQ), and two generic questionnaires, EuroQol-5D and SF-36. The evaluation of the health care utilization included visits to PC, visits of care nursing and visits to accident and emergency (A&E) department and admissions. Statistical analysis: average ± standard deviation (SD), frequency and proportions. Inferential statistics in terms of average HRQOL and health care utilization were calculated using T-Student, Chi-square and ANOVA. **RESULTS:** Average patients were female (60%), aged 49 years old (SD 2.16) with disease duration of 92 months (SD 18.34). The average health care utilization was: 3.43 (SD 0.35) visits to PC and 1.42 (SD 0.29) visits to nursing; analytical: 0.63 (SD 0.09), chest x-ray: 0.38 (±0.08), ECG 0.32 (SD 0.08). The average of exacerbations without hospital admission was 1.09 (SD 0.19) and the A&E department visits of PC related with asthma was 0.43 (SD 0.11). Statistically significant differences (p<0.05) and clinically significant between the beginning and end of the study on all forms of quality of life measured in these patients were found measured with AQLQ, EuroQol-5D and SF-36. The evaluation of the health care utilization improved visits to PC, visits of care nursing and visits to accident and emergency (A&E) department and admissions.

**CONCLUSIONS:** Beclomethasone/formoterol improved HRQOL in patients with asthma representing a good cost/utility relationship.