

**PRS26**

**THE EXACT-PRO INITIATIVE: DEVELOPMENT AND VALIDATION OF A SINGLE PATIENT-REPORTED OUTCOME MEASURE FOR EVALUATING EXACERBATIONS OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE**

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**OBJECTIVES:** To develop and validate a patient-reported outcome (PRO) instrument for measuring frequency, severity, and duration of COPD exacerbations in international trials. **METHODS:** Multi-sponsor initiative involving experts and the FDA. **Phase I:** Instrument development informed by literature and qualitative data from focus groups and interviews with U.S. COPD patients. International experts addressed concept relevance, transferability, translation ease. **Phase II:** Prospective, 2-group, observational study of patients with 1) confirmed exacerbation (PDA diary Days 1–28 and 60–67) or 2) stable COPD (PDA for 7 days). Item analyses and Rasch IRT were used to reduce the items from 23 to 14. Validity testing included known-group differences and relationship to clinical history, SGRQ-C, and clinician and patient assessment of exacerbation severity. **RESULTS: Phase I:** N = 83; 45% male; 16% African American; 13% Hispanic; mean age = 65 ( $\pm 10$ ); stable FEV-1 = 44% pred ( $\pm 16$ ). **Phase II:** N 410 (222 acute; 188 stable); 48% male; mean age = 65 ( $\pm 10$ ); stable FEV-1 = 51% pred ( $\pm 20$ ). Factor analyses supported a unidimensional structure suitable for Rasch analysis. Overall chi-square = 149.3 df = 84; person-separation index = 0.92. Three respiratory domains (breathlessness (5 items), cough-sputum (2 items), chest symptoms (3 items)) account for 68% of the variance; 4 items address systemic manifestations. Internal consistency (Day 1, N = 410) total = 0.91; domains = 0.87; 0.69; 0.87. Reproducibility (ICC) in stable patients (n = 171) Day 1 to 7 = 0.77; 0.71; 0.65; 0.64. Correlation with SGRQ-C Day 1 (N = 395): r = 0.64; 0.66; 0.35; 0.46 ( $p < 0.0001$ ). Significant differences in scores were found across exacerbation severity Day 1 ( $p < 0.001$ ) and between responders and non-responders Days 1 to 10 ( $p < 0.0001$ ). **CONCLUSIONS:** The EXacerbations of Chronic Pulmonary Disease Tool (EXACT) is a 14-item diary for evaluating exacerbation outcomes of COPD with measurement properties demonstrated to be adequate for use in clinical trials with a similar population.

**PRS27**

**INTERPRETING SCORES ON THREE PATIENT-REPORTED OUTCOME MEASURES FOR ASTHMA**

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**OBJECTIVES:** To aid interpretation of scores on the Asthma Life Impact Scale (ALIS; scored 0–22), COPD and Asthma Sleep Impact Scale (CASIS; scored 0–100) and COPD and Asthma Fatigue Scale (CAFS; scored 0–100). These new patient reported outcome measures, designed for use in clinical trials, have previously been shown to be reliable and valid. **METHODS:** Questionnaire data from UK (n = 140; 29.3% male; mean age = 50.6 years) and US (n = 185; 25.9% male; mean age = 46.0 years) surveys were analysed. Mean questionnaire scores were evaluated against clinician severity rating and by exacerbation status (US only). Effect sizes (ES) and standard errors of measurement (SEM) gave a preliminary estimate of the minimal important difference (MID). **RESULTS:** Scores on all three measures were significantly related to clinician rating of asthma severity ( $p < 0.001$ ) and patients who had had an exacerbation in the

previous week had significantly ( $p < 0.05$ ) worse scores on all measures. For the ALIS the values for 0.3 ES, 0.5 ES and SEM were 1.9, 3.2 and 1.7 respectively. For the CASIS the figures were 5.3, 8.8 and 5.2 and for the CAFS; 7.2, 12.0 and 5.4. Therefore these distribution-based analyses suggest that the MID is in the region of two for the ALIS, five for the CASIS, and seven for the CAFS. **CONCLUSIONS:** The analyses provide preliminary information on how to interpret scores on the scales. Further analyses of longitudinal data are required to confirm these findings, to assess anchor-based estimates and to allow greater precision in powering studies using these questionnaires.

**PRS28**

**HAS ASTHMA CONTROL IMPROVED SINCE AIRE? RESULTS OF A SURVEY IN 5 EUROPEAN COUNTRIES**

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**OBJECTIVES:** According to the GINA guidelines, asthma control can be achieved and maintained in a majority of patients. The 1999 AIRE study showed that only 5% of the adult asthmatic patients were controlled. Several years later, how does the situation look like? **METHODS:** Population based cross-sectional survey was carried out in 2006 in France, Germany, Italy, Spain, and the UK. A detailed questionnaire was administered to a sample of adult individuals drawn from an Internet panel. The Asthma Control Test (ACT<sup>TM</sup>) was used to assess the level of control: Total Control (TC, score = 25), Well controlled (WC, score = 20–24) and not well-controlled (NWC, score <20). **RESULTS:** Among the 37,476 individuals who participated, 2,337 had been diagnosed with asthma by a physician. 80% used rescue medication 2–3 times a week, 58% woke up once a week due to asthma, 70% had shortness of breath 3–6 times /week. Overall, 55% of asthmatic patients were not controlled despite being treated, ranging from 45% to 72%. **CONCLUSIONS:** This survey suggests the level of asthma control has improved since AIRE. However, the majority of patients still remain uncontrolled. Further efforts are required to translate the GINA recommendations to prevent symptoms and ensure patients achieve and maintain control into reality.

**PRS29**

**SOCIOECONOMIC ANALYSIS OF SMOKER'S PROFILE WHO INTENDS TO QUIT**

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**OBJECTIVES:** Depressed socio-cultural and economic groups tend to smoke more than the others. We aimed to determine socioeconomic level related aspects of the smoker's profile who intends to stop smoking. **METHODS:** A total of 1634 smokers older than 18, attended by General Practitioners and Specialized Physicians in Spain, were included in a multicentric cross-sectional survey study performed in February–June 2007. After being asked about their intention of smoking cessation, all of them were determined to or had taken some action to quit smoking within the previous 15 days. Socio-demographic data, taking into account socio-economic indicators, history of smoking and reasons to stop smoking were collected. Descriptive statistical analysis was performed. **RESULTS:** The analysed population included 1618 subjects from 167 centers fulfilling all the selection criteria. Their mean age was  $45.6 \pm 12.0$  and 56% were men. The majority (67.8%) had studied beyond high school

and most of them (76.0%) were active workers. Daily mean cigarette consumption during working days was  $20.7 \pm 9.9$ . Mean annual expenses for cigarettes reached  $\text{€}961.5 \pm 442.3$  and the median expense was  $\text{€}876$ , although significant differences ( $p < 0.0001$ ) within gender, age groups, educational level, work situation and geographic area were observed. Men older than 46–65 years showed the highest expense, regardless of their income; and unemployed workers spent more than active workers on tobacco. A mean annual expense for cigarettes higher than  $1500 \text{ €}$  was associated with a higher use of smoking cessation treatments ( $p = 0.0009$ ). However, less than 0.9% of smokers wanted to stop smoking due to economic reasons. **CONCLUSIONS:** Smokers who want to quit smoking spend annually a mean of  $\text{€}961.5$  (median of  $\text{€}876$ ) on cigarettes, although there are significant differences within socio-demographic profiles. The higher the expenses for cigarettes are, the higher the expenses for smoking cessation treatments reach.

## PRS30

#### HOW CONGRUENT ARE PATIENT AND CLINICIAN MODELS OF ASTHMA CONTROL?—PRELIMINARY FINDINGS FROM A QUALITATIVE STUDY

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**OBJECTIVES:** Recent regulatory guidelines emphasize the importance of patient input in the development of patient reported outcome (PRO) measures that will be used as clinical trial endpoints to support labelling claims. In asthma prevention and management, consensus among clinicians is growing regarding models of asthma control. It is uncertain how closely patient models concur with clinical perspectives of asthma control. The objective of this research was to develop a conceptual model of asthma control based on both patient and clinician input and explore the congruence of patient and clinical perspectives. **METHODS:** Fifty-five patients discussed the concept of asthma control in 8 focus groups (2 each in France, Germany, UK & US). Independently two asthma specialists and two general practitioners were interviewed in each country (18 in total) about their understanding of asthma control, symptoms and treatments. Data was analyzed using thematic analysis techniques based on grounded theory, and conceptual models were developed for patient and clinician perspectives. **RESULTS:** When asked what asthma control meant to them, patients talked about symptoms, sleep disturbance, tiredness, rescue medication use, activity limitations, the experience of asthma attacks and experiencing panic and fear. Clinicians focussed primarily on presence and severity of symptoms and medication use, but also mentioned the ability of the patient to remain active, patients' hospitalisation, and satisfaction with and adherence to medication as being indicators of asthma control. **CONCLUSIONS:** Our research suggests that patient and clinician models are complementary, but not completely consistent. Both emphasize symptom control and rescue medication use as key indicators. Patients, however, also consider emotional responses, tiredness and activity limitations as important, whereas clinicians more often considered adherence and health care utilisation. Differences in the models support the importance of including both patient and clinical perspectives when developing PRO measures for clinical trials.

#### A SURVEY OF THE BURDEN OF ALLERGIC RHINITIS IN EUROPE

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**OBJECTIVES:** The perceptions of patients and physicians regarding the symptoms and impact of allergic rhinitis (AR) were assessed in a prospective, international, cross-sectional survey using a convenience sample of consulting patients. We present the combined survey results from Germany, France, Italy, Spain and UK. **METHODS:** Data were recorded by 1482 patients and matched with records completed by primary care physicians and specialists. Diagnostic tests to confirm AR had been performed on 1279 (86.3%) patients. Both physicians and patients recorded the presence, severity and impact of symptoms. Health-related quality of life (HRQoL) was assessed. **RESULTS:** A large proportion of patients had moderate-severe disease (67.2%;  $n = 996$ ), persistent disease (42.5%;  $n = 630$ ) and co-morbidities such as asthma (31.5%;  $n = 467$ ). Patients generally rated their disease as more severe than did their physicians ( $P < 0.001$ ). At the time of the consultation, one-third of all patients reported that their current nasal and ocular symptoms were moderate or severe in nature. According to the physicians' assessment, good control of nasal and ocular symptoms was achieved in 45.4% ( $n = 673$ ) and 51.3% ( $n = 760$ ) of patients, respectively. Overall, 43.3% ( $n = 641$ ) of those surveyed were using two or more medicines for their AR. HRQoL was correlated with disease severity and with the number of days without symptoms in the previous 4 weeks. AR had a significantly greater impact in patients with more persistent disease than in those with intermittent disease ( $2.3 \pm 1.3$  vs.  $1.9 \pm 1.2$ ;  $P < 0.001$ ). Nonetheless, 81.8% ( $n = 601$ ) of patients with intermittent disease reported some impairment of their daily life as a result of their AR. **CONCLUSIONS:** AR remains a significant health problem because of the high burden of symptoms and its impact on general well being and HRQoL.

## PRS32

#### SYMPTOMS AND IMPACT OF SYMPTOMS AS REPORTED BY ASTHMA PATIENTS

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**OBJECTIVES:** Shortness of breath, chest tightness, wheeze and cough are hallmark symptoms of asthma. These can significantly impact a patient's life causing impairment to a patient's physical, emotional and social wellbeing. To evaluate a treatment's efficacy, it is important to assess endpoints that are important to patients. This study aimed to confirm symptoms and their impact which are important to asthma patients. **METHODS:** Fifteen patients with asthma, meeting predefined inclusion criteria were recruited by MAPI Values in Boston, USA. All patients consented. The semi-structured interviews explored symptoms and impact of symptoms. Patients also completed the Asthma Control Test<sup>TM</sup> (ACT) and the Asthma Quality of Life Questionnaire (AQLQ(S)). Taped interviews were transcribed maintaining anonymity and analysed to answer the key questions in the interview guide. Findings of the first 11 (75%) interviews were compared with the final 4 (25%) interviews to determine the level of consistency in the pattern of responses. **RESULTS:** All