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 (FDA diary Days 1–28 and 60–67) or 2) stable COPD (FDA 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 ±10; stable FEV1 = 44% pred (±16). Phase II: N = 410 (222 acute; 188 stable); 48% male; mean age = 65 ±10; stable FEV1 = 51% pred±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 = 393): r = 0.64; 0.66; 0.53; 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.

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.

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.

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 = 183; 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.

Socioeconomic Analysis of Smoker’s Profile Who Hesitates 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 ± 12.0 and 56% were men. The majority (87.8%) had studied beyond high school.