was conducted. **RESULTS: Overall, 20,488 cases were included in the analysis. After** the adjustment for age, sex, body-mass-index and duration of education there is a statistically significant association between consumption of tobacco and HRQoL in all subscores as well as both composite scores of the SF-12. The regression coefficients for current smoking (all non-smokers as reference group) are relatively small with –0.68 (role physical) to –1.35 (general health) points for physical domains and between –0.58 (vitality) and –1.47 (mental health) points for mental domains. These differences increase considerable for elderly persons (age of 50 or older, N = 9830) with –1.274 (role physical) to –1.87 (general health) points for physical and –0.953 (vitality) to –1.682 (social functioning) for mental scales. Equally, there is a strong statistical association between the current amount of smoking (per 10 cigarettes per day) and HRQoL (–0.342 to –0.858 for physical and –0.47 to –1.07 for mental domains, N = 5560). **CONCLUSIONS: In particular, the findings are limited by the** inconclusive causality direction for smoking and mental health. However, these results confirm the existing evidence concerning the negative association between smoking status or smoking intensity and HRQoL in a general population.

PRS39

VALIDATION OF THE SPANISH VERSION OF THE "COPD AND ASTHMA SLEEP IMPACT SCALE (CASIS)" QUESTIONNAIRE

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OBJECTIVES: To validate the Spanish version of the specific questionnaire "COPD and asthma sleep impact scale (CASIS)" which measures the impact of sleep quality in patients with COPD on their HRQoL. **METHODS:** Observational, prospective, multicenter study in patients with moderate/severe COPD. Data were collected at inclusion and at day 15, including the Spanish version of CASIS (7 items, range: 7 best–35 worst) and the "gold standard" Saint George Respiratory Questionnaire (SGRQ). Additionally, socio-demographics, clinical data and one item about self-perceived change in health status between visits were recorded. Feasibility, validity, reliability (internal consistency, test-retest) and responsiveness to change of the CASIS Spanish version were evaluated. **RESULTS:** A total of 142 patients were included, 87.1% males, mean age (SD) was 67.4(8.2) years, 52.7% with primary studies, 75% former smokers, FEV_1 (%) = 48.5%, (SD = 13.3), 51.3% stage II, 37.6% stage III and 11.1% stage IV. Mean (SD) score in CASIS was 18.5(6.5). CASIS questionnaire showed low levels of absent information: the mean number of items not responded per patient was <0.1, and no item accumulated more than 1 missing response. Ceilling effects of CASIS (proportion of patients accumulated in the maximum possible score) were null, and floor effects (proportion of patients accumulated in the minimum possible score) were 7.5%. CASIS showed low internal consistency (Cronbach's alpha <0.50) but an excellent test-retest reliability among patients who reported subjective stability in their health status (inter-class correlation coefficient = 0.88). Correlations between CASIS and SGRQ global scores were high (0.71) and correlations between CASIS and SGRQ dimensions were moderate to high (0.62 to 0.69). Significant differences ($p < 0.01$) in LCOPD were observed in exacerbated patients who reported an improvement, with a high effect size (0.90). **CONCLUSIONS:** According to preliminary results, Spanish version of CASIS showed satisfactory psychometric properties in terms of feasibility, validity, reliability and responsiveness to change.

PRS40

IMPACT OF COUGH AND/OR SPUTUM SYMPTOMS ON HEALTH-RELATED QUALITY OF LIFE IN COPD PATIENTS: AN OBSERVATIONAL, CROSS-SECTIONAL STUDY IN EUROPE AND THE USA

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OBJECTIVES: It is hypothesised that cough and/or sputum symptoms have a negative impact on health-related quality of life (HRQoL) in chronic obstructive pulmonary disease (COPD). This study assessed the impact of these symptoms on HRQoL in 396 COPD patients. **METHODS:** Data were drawn from the Respiratory Adelphi Disease Specific Programme conducted in France, Germany, Italy, Spain, the UK and the USA in 2008. Information collected included physicians' perceptions of symptom severity. Patients were invited to fill out a questionnaire that included EQ-5D. Variables analysed were age, gender, body mass index, breathlessness, smoking status, co-morbidities (heart-related and anxiety/depression), compliance, most recent forced expiratory volume in 1 second (FEV_1, if available) and country of origin. Due to a highly skewed EQ-5D distribution, three regression methods were applied (Tobit, OLS and GLM) to assess the impact of these variables on HRQoL. Final models derived included statistically significant variables only ($p < 0.05$). **RESULTS:** Using all three methods, cough and/or sputum were significant predictors of worse HRQoL compared with COPD patients not experiencing these symptoms. FEV_1 was only a significant predictor of better HRQoL in the Tobit approach. In this model, patients with moderate or severe cough and/or sputum symptoms presented with worse HRQoL compared with the wider COPD population (-0.09, 95% CI –0.14, –0.04). FEV_1 values 30–50% predicted are associated with higher EQ-5D (0.006, $p < 0.05$). However, no further significant impact was present at FEV_1 >50% predicted. In the Tobit model, patients not viewed as fully compliant with the current drug regimen were also associated with worse EQ-5D (–0.09, $p < 0.05$). Similar statistically significant variables were observed using the GLM and OLS models. **CONCLUSIONS:** Presence and severity of cough and/or sputum in COPD has a marked association with worse HRQoL, independent of FEV_1 measurements. These results indicate unmet therapeutic needs in this population.

PRS41

VALIDATION OF THE SPANISH VERSION OF THE "LIVING WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (LCOPD)" QUESTIONNAIRE

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OBJECTIVES: To validate the Spanish version of the quality of life (QoL) specific questionnaire for patients with COPD "Living with Chronic Obstructive Pulmonary Disease" (LCOPD). **METHODS:** Observational, prospective, multicenter study in a sample of patients with moderate/severe COPD. Data were collected at inclusion and at day 15, including the Spanish version of LCOPD (22 items, range: 22 worst—44 best) and the "gold standard" Saint George Respiratory Questionnaire (SGRQ). Additionally, socio-demographics, clinical data and one item about self-perceived change in health status between visits were recorded. Feasibility, validity, reliability (internal consistency, test-retest) and responsiveness to change of the LCOPD Spanish version were evaluated. **RESULTS:** A total of 142 patients were included, 87.1% males, mean age (SD) was 67.4 (8.2) years, 52.7% with primary studies, 75% former smokers, FEV_1 (%) = 48.5%, (SD = 13.3), 51.3% stage II, 37.6% stage III and 11.1% stage IV. Mean (SD) score in LCOPD was 33.0 (6.7). LCOPD questionnaire showed low levels of absent information: the mean number of items not responded per patient was <0.1, and no item accumulated more than 1 missing response. Floor and ceiling effects of LCOPD (proportion of patients accumulated in the minimum and maximum possible scores, respectively), were low (6%). LCOPD showed satisfactory levels of reliability: high internal consistency (Cronbach's alpha = 0.94) and excellent test-retest reliability among patients who reported subjective stability in their health status (inter-class correlation coefficient = 0.92, $p < 0.001$). Correlations between LCOPD and SGRQ global scores were very high (0.85), and correlations between LCOPD and SGRQ dimensions were moderate to high (0.60 to 0.87). Significant differences ($p < 0.05$) in LCOPD were observed in exacerbated patients who reported an improvement, with a small to moderate effect size (0.31). **CONCLUSIONS:** According to preliminary results, Spanish version of LCOPD showed satisfactory psychometric properties in terms of feasibility, validity, reliability and responsiveness to change.

PRS42

VALIDATION OF THE SPANISH VERSION OF THE "COPD AND ASTHMA FATIGUE SCALE (CAFS)" QUESTIONNAIRE

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OBJECTIVES: To validate the Spanish version of the health specific questionnaire to evaluate the impact of fatigue on patients with COPD "COPD and asthma fatigue scale (CAFS)". **METHODS:** Observational, prospective, multicenter study in a sample of patients with moderate/severe COPD. Data were collected at inclusion and at day 15, including the Spanish version of CAFS (12 items, range: 12 best–60 worst) and the "gold standard" Saint George Respiratory Questionnaire (SGRQ). Additionally, socio-demographics, clinical data and one item about self-perceived change in health status between visits were recorded. Feasibility, validity, reliability (internal consistency, test-retest) and responsiveness to change of the CAFS Spanish version were evaluated. **RESULTS:** A total of 142 patients were included, 87.1% males, mean age (SD) was 67.4 (8.2) years, 52.7% with primary studies, 75% former smokers, FEV_1 (%) = 48.5%, (SD = 13.3), 51.3% stage II, 37.6% stage III and 11.1% stage IV. Mean (SD) score in CAFS was 36.7 (12.1). CAFS questionnaire showed low levels of absent information: the mean number of items not responded per patient was <0.1, and no item accumulated more than 1 missing response. Floor and ceiling effects of CAFS (proportion of patients accumulated in the minimum and maximum possible scores, respectively), were low (<2%). CAFS showed satisfactory levels of reliability: high internal consistency (Cronbach's alpha = 0.88) and excellent test-retest reliability among patients who reported subjective stability in their health status (inter-class correlation coefficient = 0.85). Correlations between CAFS and SGRQ global scores were high (0.79), such as the correlations between CAFS and SGRQ dimensions (0.63 to 0.74). Significant differences ($p < 0.01$) in LCOPD were observed in exacerbated patients who reported an improvement, with a high effect size (0.90). **CONCLUSIONS:** According to preliminary results, Spanish version of CAFS showed satisfactory psychometric properties in terms of feasibility, validity, reliability and responsiveness to change.

PRS43

RELIABILITY AND VALIDITY OF THE SMOKER COMPLAINT SCALE

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OBJECTIVES: The aim of this study was to determine the reliability and validity of the Smoker Complaint Scale for the Turkish population. **METHODS:** The research was conducted in the university students. For pretest study forty students were chosen as a sampling group. After the assessment of the results, the Smoker Complaint Scale was applied to 250 students who quit smoking. Of the students are 54% female and 46% male. The original instrument was translated into Turkish and then translated back into English by two independent translators. For psychometric measures, a small sample was used to check the initial comprehension and factibility. Cronbach's Alfa was used to assess reliability and factor analysis to assess dimensionality. The EuroQol-5D was used for concurrent validity. **RESULTS:** The internal consistency coefficient (Cronbach's alpha) of SCS was 0.912. Factor analysis of the scale revealed that it was composed of 5 factors with Eigenvalues >1.0, accounting for 77.9% of the total variance. All the items of the Turkish SCS had a factor load ranging from 0.587

to 0.886 and they all belonged to 5 factors. There was a strong relationship between SCS and EuroQol 5D (r = between 0.46–0.76). **CONCLUSIONS:** The research suggests that the validity and reliability of the Turkish SCS are satisfactory and that it can be used in Turkey.

PRS44

CLINICO-PHARMACOLOGICAL PRESENTATION AND THE OUTCOME OF QUALITY OF LIFE OF PATIENTS WITH EXACERBATION OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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OBJECTIVES: Determine quality of life of COPD patients. **METHODS:** The medical records of 300 patients with acute exacerbation of COPD who visited City Clinical Hospital #2, with mean age 68.5 ± 4.5 male and 64.8 ± 3.4 female, were retrospectively reviewed. Patients were evaluated on the criteria for COPD [2006]. Sociodemographic data, severity of disease, co-morbidity, and use of health resources in the previous years were collected. SF-36 quality of life questionnaire were administered to all patients. **RESULTS:** The mean FEV_1 value was 45.9 ± 9.1%. The severity of the disease was mild in 139 (46.3%) cases, moderate in 114 (38.0%), severe in 30 (10.0%), very severe in 17 (5.7%). With regard to the use of health resources in the previous year, the mean values were: visits to physician 7,27 ± 1,2 and hospital admissions 8,16 ± 0,31. The mean SF-36 scores for patients with mild COPD in the physical component before and after therapy were 84.5 ± 4.2 and 91.2 ± 5.8 with Δ % value (9.2 ± 1.6); moderate 73.2 ± 3.1 and 77.6 ± 4.6 with Δ % value (6.0 ± 1.5); severe 42.2 ± 1.2 and 45.2 ± 2.6 with Δ % (4.5 ± 1.4); very severe 19.8 ± 2.4 and 23.5 ± 3.8 with Δ % value (4.2 ± 1.4). Similarly, the mean SF-36 scores on mental component of all groups of patients under study, ranging from mild to very severe were 69.60 ± 2.1 and 72.3 ± 3.4 with Δ % value (3.1 ± 2.3); 54.6 ± 2.2 and 56.9 ± 3.7 with Δ % value (4.2 ± 1.5); 38.0 ± 2.3 and 39.6 ± 3.1 with Δ % 3.9 ± 0.8; 28.2 ± 1.1 and 29.1 ± 2.4 with Δ % value (4.2 ± 1.3). **CONCLUSIONS:** Patients had an increase functional dynamic index (Δ %) of SF-36 in the physical component, and significant reduction was only seen in mental component of patients with severe and very severe cases.

RESPIRATORY-RELATED DISORDERS – Health Care Use & Policy Studies

PRS45

CLINICAL AND ECONOMIC OUTCOME OF MECHANICALLY VENTILATED PATIENTS UNDER DRG 475: A POPULATION-BASED STUDY

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OBJECTIVES: Mechanical ventilation for acute respiratory failure is likely to be a reliable indicator of critical care resource requirements on a population level. Our aim is to analyze the costs and discharge status for patients with respiratory failure needing mechanical ventilation (DRG code 475) in Spain and to examine the impact of age in terms of hospital outcome. **METHODS:** From the 2004 National Hospital Discharge Database all records aged >16 years with a final DRG 475 were retrieved. This DRG, defined as "respiratory system diagnosis with mechanical ventilation", includes three procedure codes and is applied to patients undergoing mechanical ventilation for a variable period of time. Demographic characteristics, clinical outcomes and hospital-resources utilization were examined. An exploratory logistic regression analysis was performed to identify factors associated with in-hospital mortality. To depict the amount of resources spent to procure a given level of desired outcome (hospital survival) we determined the cost per survivor based in the average national charges for DRG 475. **RESULTS: 4267 cases were eligible for analysis. Mean age was 64 yr, 71%** were men and 85% medical patients. According to Charlson index, 45% of cases had no associated comorbidity. Overall 36% of cases required prolonged mechanical ventilation. In-hospital mortality was 39%. Median LOS was 14 days. Total hospital costs were [a] 42,581,929. Multivariate logistic regression showed that age significantly correlated with in-hospital mortality after adjusting for comorbidities, principal cause of hospital admission and duration of mechanical ventilation. An inverse relationship between survival rate and age was observed and this resulted in an age-related increased cost per survivor. **CONCLUSIONS: Age has a significant impact on outcomes** in patients under DRG 475. These analyses will help inform health care decision-making and resource planning in the face of an ageing population. **This study** has been supported by the Spanish National I+D Program (grant number **STPY** 1456/07**).**

PRS46

OFF-LABEL PRESCRIBING OF INHALED CORTICOSTEROID/ LONG ACTING BETA-AGONIST COMBINATION PRODUCTS IN COPD PATIENTS

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OBJECTIVES: Despite different licences for the use of inhaled corticosteroids/ long acting beta—agonist combination products for Chronic Obstructive Pulmonary Disease (COPD) and asthma, anecdotal evidence suggests general practitioners prescribe similar formulations and doses for both diseases. For patients with COPD, where the licences are more restricted, this may lead to "off-label" prescribing. The objective of this study was to examine the frequency and nature of "off-label" prescribing of combination products in COPD patients. **METHODS:** This was a retrospective cohort study using data from the General Practice Research Database (GPRD), a large nationally representative UK primary care database. All combined salmeterol/fluticasone and formoterol/budesonide prescriptions written between Jan 2006 and Dec 2007 for patients with a Read code for COPD were selected. "Off-label" prescribing was defined as any formulation and/ or dose of salmeterol/fluticasone or formoterol/budesonide not licensed for COPD. The proportion of "off-label" prescriptions was calculated for each of the 2 treatments and "off-label" prescriptions were further subdivided into whether they were "off-label" with respect to formulation or dose. All calculations were replicated at the patient level and reported in relation to age, sex and smoking status. **RESULTS:** The analyses were based on a total of 21,137 COPD patients receiving combination products (salmeterol/fluticasone: 17,115; formoterol/budesonide: 4,809) between 2006–2007. 77% of prescriptions were "off-label", 71% for an incorrect formulation and 6% for an incorrect dose. 86% of salmeterol/fluticasone prescriptions were "off-label" (85% formulation, 1% dose) versus 37% of formoterol/budesonide prescriptions (10% formulation, 27% dose). The most frequently prescribed unlicensed formulations were salmeterol 25 mcg/fluticasone 250 mcg pMDI (45%) and salmeterol 25 mcg/fluticasone 125 mcg pMDI (20%). **CONCLUSIONS:** "Off-label" prescribing of combination therapy in COPD patients is very common in the UK. The impact of off-label prescribing on efficacy and patient safety is unknown; "off-label" prescribing potentially represents an economically wasteful prescribing practice.

PRS47

SEASONAL VERSUS NEEDS-BASED IMMUNIZATION SCHEDULES—THE EXAMPLE OF RSV

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OBJECTIVES: Due to cost reaching $10,000/season, respiratory syncytial virus (RSV) immunoprophylaxis is limited to high-risk periods, but season determination is heavily debated and absolute risk varies significantly by geographic location. We present monthly RSV incidence rates to estimate absolute burden of disease and numbers needed to treat (NNT) to provide an alternative to a dichotomous season definition. **METHODS:** Medicaid fee-for service recipients <2 years old from California and Florida (1999–2004) were selected if they met high-risk criteria for RSV infections (chronic lung disease or congenital heart disease based on ICD-9 codes, or prematurity up to 32 weeks' gestational age based on birth certificates). Monthly RSV hospitalization rates were broken down by recipients' age and adjusted for the effects of immunoprophylaxis. NNTs were calculated as inverse of the absolute risk reduction (based on relative risk reduction from clinical trial data: 50%). Results in Florida were separated in 5 surveillance regions. **RESULTS:** California showed a very distinct season from December–March with almost zero viral activity outside. NNTs were smallest in February (<50) but increased with increasing age. In Florida, no months had zero activity; however, NNTs were never below 125, regardless of age. Among children >1 year, the lowest NNT was 252 [95% CI: 129–5,875] and NNTs exceeded 500 for 8 months (January–August). While the northern regions showed a short, distinct season, the southern regions experienced prolonged activity, most obvious in the southeast. Yet, April through July in the southwest and May/June in the southeast showed NNTs exceeding 650 while the winter months had a peak activity that was comparable to other regions. **CONCLUSIONS:** NNTs can address differences in burden of disease during the RSV season and between geographic regions and assure equitable access to prophylaxis. Reduced RSV incidence in the second year of life should be incorporated in decisions for immunoprophylaxis.

PRS48

A SURVEY OF TOBACCO CESSATION INTERVENTIONS IN THE DENTAL SETTING IN JAPAN: NICOTINE REPLACEMENT THERAPY, ATTITUDES TOWARDS TOBACCO CESSATION EDUCATION, AND BARRIERS TO CESSATION COUNSELING

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OBJECTIVES: Tobacco has been identified as a major risk factor for lung cancer, heart disease, and respiratory disease. Adults rarely visit their physicians for preventive care. But surveys have shown that more than half of adult smokers see a dentist each year for preventive care. This may put dentists in a better position to implement tobacco cessation interventions. The aim of the study was to investigate the tobacco cessation interventions conducted by dental practitioners in Japan. **METHODS:** The study used a survey mailed to dentists (n = 1489) in three prefectures (Tokyo, Iwate, Yamanashi) asking about the practitioners' tobacco cessation activities, patient demographic characteristics, barriers to counseling, and attitudes towards tobacco in 2008. **RESULTS:** The response rate was 57% (n = 847). Dentists advised 22% of patients to cease tobacco. More than half of them used a pamphlet or other printed materials. However, nicotine replacement therapy was prescribed infrequently (nicotine patches in 3.2% and nicotine gum in 2.2% of patients). Asked whether dentists should perform tobacco cessation interventions in their offices, 76% said yes. The main barrier to cessation counseling was insufficient time, followed by a lack of knowledge and tobacco cessation specialists to whom to refer patients. 85% of respondents had no education or training in promoting tobacco cessation. Twenty-two percent of all respondents were smokers. **CONCLUSIONS:** Few dentists perform tobacco cessation interventions in their offices. Nicotine replacement therapy was hardly prescribed at all. Dentists have a positive attitude towards tobacco cessation interventions and