the disease was developed and the study adopted society's perspective while the horizon time considered was patient's remaining lifespan. Cohorts of COPD patients treated with Tiotropium or cohorts of patients undergoing pulmonary rehabilitation programs were simulated (Monte-Carlo simulations in TreeAge software) and compared to identical cohorts of patients subjected to usual care. Life expectancies, quality adjusted life-years (QALY), disease-related costs, and incremental cost-utility ratios were estimated. **RESULTS:** At the horizon of a patient's remaining lifetime (14.29 life years in average, considering a population combining moderate to very severe patients), tiotropium would result in 0.12 life years and 0.58 QALY gained (mean estimates), induce an additional cost of 5380 €/patient in the disease-related costs, with a corresponding incremental cost-utility ratio of 8853 €/QALY. For pulmonary rehabilitation programs, these estimates were 0 life years, 0.31 QALY, 2,969 €, and 12,000 €/QALY, respectively. Results were mostly sensitive to the utility changes associated with exacerbations. **CONCLUSIONS:** Tiotropium treatment and pulmonary rehabilitation programs were estimated as worth interventions in the studied population, below the usual threshold used for declaring procedures as cost effective. Nevertheless, the modest gains in health issued from the study emphasize the need of research for developing more effective COPD-related therapies.

PRS47

OPTIMA MODEL-BASED COST-UTILITY ANALYSIS OF FIXED COMBINATION SALMETEROL/FLUTICASONE VERSUS NON-FIXED COMBINATION BUDESONIDE/FORMOTEROL IN ONE PACK FOR BRONCHIAL ASTHMA TREATMENT

Yagudina R[1], Kulikov A[1], Chuchalin AG[2], Ogorodova LM[3], Demko IV[4], Lomakin A[5], Shchurov D[6]

[1]*I.M. Sechenov First Moscow State Medical University, Moscow, Russia,* [2]*SRI of Pulmonology, Moscow, Russia,* [3]*Siberian State Medical University, Tomsk, Russia,* [4]*Krasnoyarsk State Medical University, Krasnoyarsk, Krasnoyarsk, Russia,* [5]*GlaxoSmithKline Russia, Moscow, Russia,* [6]*GlaxoSmithKline, Moscow, Russia*

OBJECTIVES: To assess costs, utilities and cost-utility of fixed combination salmeterol/fluticasone (SAL/FP maintenance treatment) versus non-fixed combination budesonide + formoterol in one pack (BUD+FORM maintenance treatment) in the management of patients with bronchial asthma by means of an OPTIMA model. **METHODS:** In this analysis we used the following data: drug prices (from List of Maximum Permissible Manufacturer Prices for Vital and Essential Drugs) and drug dosage proportion (from MRC Pharmexpert, 4Q 2010); number of inhalations per day (from instructions); QOL and number of health care resources for controlled and uncontrolled asthma (from published sources); resource unit costs (from 2010 health care insurance program). Work-off day costs included tax deficiency, GDP underproduction and sick pay. Frequency of controlled asthma was obtained from ARROW study (Ogorodova et al., 2009) for SAL/FP (73%) and from FACET trial (O'Byrne et al. 2008) for BUD+FORM (62%). Conceptual formula of analysis was: cost of drugs + % controlled * cost of controlled + % uncontrolled * cost of uncontrolled. One-way sensitivity analysis was conducted to assess the robustness of the results. **RESULTS:** Average monthly costs of drugs were 1,677 RUR/€42 and 2,023 RUR/€51 for SAL/FP and BUD+FORM respectively. Medical costs and QOL measures were 378 RUR/€9 and 0.75 for controlled asthma; 88,295/€2,207 RUR and 0.49 for uncontrolled asthma. Yearly total costs per patient were higher for BUD+FORM than for SAL/FP (58,057/€1,451 RUR vs. 44,244 RUR/€1,106). Compared to BUD+FORM, SAL/FP was associated to an expected increase of QALYs per patient (0.68 QALYs vs. 0.65 QALYs). The cost-utility analysis showed that SAL/FP was dominant (less costly and more effective in terms of QALYs gained). Results were sensitive to all the parameters varied in the sensitivity analysis, especially health care costs. **CONCLUSIONS:** Treatment of patients with bronchial asthma with SAL/FP is a dominant strategy in comparison with non-fixed combination BUD+FORM in one pack.

PRS48

COST-UTILITY ANALYSIS OF VARENICLINE VS EXISTING SMOKING CESSATION STRATEGIES IN EL SALVADOR

Lutz MA[1], Lovato P[2], Morales G[2], Cuesta G[2]

[1]*Pfizer S.A., Escazú, San Jose, Costa Rica,* [2]*Pfizer Central America and the Caribbean, Escazú, San Jose, Costa Rica*

OBJECTIVES: Smoking is the leading cause of preventable death in El Salvador (50%) and results in many serious comorbidities, including lung cancer, coronary heart disease, stroke and chronic respiratory disease. The aim of this study was to evaluate the cost-utility of varenicline compared to other existing strategies for smoking cessation within a 5-year time horizon in El Salvador using the healthcare payer's perspective. **METHODS:** The Benefits of Smoking Cessation on Outcomes (BENESCO) simulation model was used for an adult cohort (n=4,537,803). Diseases included were: stroke, lung cancer, coronary heart disease and chronic obstructive pulmonary disease. Smoking cessation therapies compared were: varenicline (0.5 – 2 mg/day), bupropion (300 mg/day), nicotine replacement treatment (NRT) (5-10 mg/day) and unaided cessation. Effectiveness measure was: quality-adjusted life year gained (QALY's), which was obtained from published literature. Resource use and costs data were obtained from El Salvador's Ministry of Health and Social Security official databases (2010). The model used a 3% discount rate for costs (expressed in 2010 US dollars) and QALYs. Probabilistic sensitivity analyses (PSA) were conducted and acceptability curves were constructed. **RESULTS:** Varenicline reduced smoking related morbidity, mortality and healthcare costs. After 5 years, Varenicline gained 306,158 QALYs, which represents 73, 94 and 178 more QALYs than bupropion, NRT and unaided cessation, respectively. Overall costs showed varenicline as the least expensive option against bupropion (+US$328,558), NRT (+US$412,730) and unaided cessation (+US$777,124). Cost-effectiveness analyses showed that varenicline was the dominant strategy. Acceptability curves showed that varenicline would be cost-effective within <3 GDP per capita threshold. PSA results support the robustness of the findings. **CONCLUSIONS:** Smoking cessation therapy with varenicline is cost-saving in El Salvador. These results could help to reduce the tobacco related disease burden and align cost-containment policies.

PRS49

ECONOMIC BURDEN ATTRIBUTABLE TO OBESITY IN ADULT PATIENTS WITH ASTHMA IN THE UNITED STATES

Suh DC[1], La HO[2], Barone J[3], Chang CW[3], Kim CM[2]

[1]*College of Pharmacy, Chung-Ang University, Seoul, NJ, South Korea,* [2]*Catholic University College of Medicine, Seoul, South Korea,* [3]*Rutgers University, Piscataway, NJ, USA*

OBJECTIVES: To estimate annual medical and productivity costs attributable to obesity in adult patients with asthma in the US. **METHODS:** This study used the 2003-2008 Medical Expenditure Panel Survey. Asthma patients(18-64 years) were identified using ICD-9-CM code 493, clinical classification code-128, or physician diagnosis. Patients were classified as normal(BMI:18.5-<25 kg/m2), overweight-(BMI:25-<30 kg/m2) or obese(BMI:≥30 kg/m2). Medical costs were estimated using a generalized linear model(GLM) with a log link function and gamma distribution. Costs associated with productivity loss were calculated based on missed working days due to illness and average hourly wage using a two part model. In the first part, logistic regression was used to estimate the probability of having missed working days due to illness. In the second part, among patients with missed working days, GLM was used with the estimated probability from first part of model to estimate the cost associated with productivity loss. The costs attributable to obesity were estimated by differences between the observed and estimated cost in obese patients, using a distribution of covariates obtained from normal patients. All costs were converted to 2010 US dollars using price indices. **RESULTS:** A total of 8775 adults were identified with asthma. The average treatment cost and lost productivity costs of normal patients were $3154(95%CI:$2689-$3620) and $327(95%CI:$279-$375), and those of obese patients were $5720(95%CI:$5314-$6129) and $699(95%CI:$608-$790), respectively. Obese patients had 38% higher medical cost and 53% higher lost productivity costs after adjusting for other study variable.Additional medical costs attributable to obesity were calculated at $1087 (95%CI:$687-$1487) and lost productivity costs attributable to obesity were $279(95%CI:$191-$368). **CONCLUSIONS:** The economic burden of asthma among US adults is substantial which is only further amplified by the presence of obesity. This study highlights the importance of obesity control to reduce the cost of treating asthma patients and enhance productivity.

PRS50

THE DUTCH 1-YEAR RESOURCE USE RESULTS FROM THE EXPERIENCE STUDY, AN INTERNATIONAL REGISTRY OF REAL-WORLD OUTCOMES FOR ASTHMA PATIENTS TREATED WITH OMALIZUMAB

van Nooten F[1], Thompson C[2], Brown R[2], Groot M[3]

[1]*United BioSource Corporation, London, UK,* [2]*United BioSource Corporation, Bethesda, MD, USA,* [3]*Novartis Pharma B.V., Arnhem, The Netherlands*

OBJECTIVES: The objective is to describe the healthcare resource utilization and cost patterns associated with severe uncontrolled allergic asthma, based on data from Dutch patients collected in the EXPERIENCE study. **METHODS:** EXPERIENCE was a prospective, open-label, observational, multicenter, multicountry study in patients with severe persistent allergic asthma treated with omalizumab. The Global Evaluation of Treatment Effectiveness (GETE) was used to evaluate patient response. Healthcare resource use and number of exacerbations were captured for one year prior to the start of the study for all patients and continued for 104 weeks until end of the study. Hospitalizations, specialist visits and medications were included in this analysis for year before study and first year of study. Unit cost prices taken from 2010. **RESULTS:** A total of 154 subjects were included in ITT population. There were 2.5 clinically significant (CS) exacerbations/patient year prior compared to 0.90 CS exacerbations/patient for year of study on omalizumab. The total number of CS severe (CSS) exacerbation was 0.95 CCS exacerbations/patient for year prior and 0.26 CSS exacerbations/patient for year of study. The results indicate that patients in this study have an average cost of €4257/patient in the year prior to the study and €2583/patient cost during the study year, excluding omalizumab costs. The biggest cost drivers are hospitalization, work days lost and other asthma medications. The total omalizumab costs were €12,652/patient plus €1,171/patient for administration cost. **CONCLUSIONS:** This study reflects real life clinical practice and associated costs for omalizumab treatment of severe allergic asthma patients. It indicates a reduction in CS and CSS exacerbation rates of 64% and 73%, respectively associated with a 40% reduction in treatment costs when using omalizumab. Keeping in mind the study limitations associated with the observational setting, it provides estimated costs for patients with severe uncontrolled allergic asthma based on 'real-world' Dutch practice patterns.

Respiratory-Related Disorders – Patient-Reported Outcomes & Preference-Based Studies

PRS51

THE DEVELOPMENT OF THE EARLY MORNING SYMPTOMS OF COPD INSTRUMENT (EMSCI)

Palsgrove A[1], Houghton K[2], Hareendran A[3], Schaefer M[1], Setyawan J[4], Mocarski M[5], Carson R[5], Make B[6]

[1]*United BioSource Corporation, Bethesda, MD, USA,* [2]*RTI Health Solutions, Manchester, UK,* [3]*United BioSource Corporation, London, UK,* [4]*Shire Pharmaceuticals, Wayne, PA, USA,* [5]*Forest Research Institute, Jersey City, NJ, USA,* [6]*National Jewish Health, Denver, CO, USA*

OBJECTIVES: To develop a self-administered patient reported outcome (PRO) instrument to evaluate patients' experience of early morning symptoms of Chronic Obstructive Pulmonary Disease (COPD). **METHODS:** A literature review and interviews with six clinical experts were performed to identify concepts for the evaluation of early morning symptoms of COPD and to develop a focus group discussion guide. Four focus groups were conducted with a total of 27 COPD patients who experienced COPD symptoms at night or in the early morning. Qualitative data was analyzed using ATLAS.ti to identify key concepts and patient terminology which were then used to create a conceptual framework and to generate items and response options for the new PRO instrument. One-on-one cognitive debriefing interviews were conducted with 10 COPD patients to assess item readability, comprehensiveness, and content validity. **RESULTS:** Focus group participants had a mean age of 68.1 years, were 51.9% female, and had a range of COPD severity levels: 7.4% GOLD I (mild), 55.6% GOLD II (moderate), 14.8% GOLD III (severe), 22.2% GOLD IV (very severe). Most of the participants experienced COPD symptoms in the early morning (n=25, 92.6%). Patients noted symptoms such as cough and impacts such as restricted morning activities. Cognitive debriefing interviews demonstrated that the items were comprehensive, relevant and interpreted as intended. A few items were edited to improve clarity based on feedback from the patients. **CONCLUSIONS:** The Early Morning Symptoms of COPD Instrument (EMSCI) is a PRO instrument developed to evaluate the full range of early morning symptoms of COPD. The instrument was developed based on patients' experiences to support content validity. The EMSCI can be used to characterize COPD patients' experience of early morning symptoms for clinical decision making and for the evaluation of new treatments.

PRS52

INPATIENT HOSPITAL CARE OR HOSPITAL-AT-HOME FOR COPD EXACERBATIONS: A DISCRETE CHOICE EXPERIMENT

Goossens L, Rutten-Van Mölken M
Erasmus University, Rotterdam, The Netherlands

OBJECTIVES: Hospital-at-home programs for COPD exacerbations aim to provide care efficiently by shortening or avoiding hospital admissions. The objective was to quantify Dutch patient and informal caregiver preferences for different aspects of hospital-at-home. **METHODS:** In a discrete-choice experiment, respondents made 14 choices between regular hospital admission (7 days) and two programs in which 3 hospital days were followed by a 4-day treatment at home. The home treatment was described by a set of attributes (see results). Hospital treatment was constant across choice sets. Respondents were patients and their informal care givers who participated in an RCT on the cost-effectiveness of hospital-at-home versus regular hospital care. The data were analyzed in latent-class conditional logit models, which allowed for heterogeneity across groups. **RESULTS:** A total of 202 questionnaires were returned. 25% of patients and caregivers always opted for hospital treatment, 46% always chose hospital-at-home. For both groups, the best fit was provided by a model with four latent classes, depending on preference for hospital and caregiver burden. All attributes had the expected sign and a significant effect on choices, except for number of home visits. Attribute levels with the strongest impact were hospital preference (for patients, coefficients (depending on class): -5.62 to +3.3), a 5h/day caregiver burden (-3.5 to -0.11) and co-payment of €100 (1.11). Also influential were specialized training for the homecare nurse (0.52), visits by many different nurses (-0.43), high readmission risk (-0.41), GP instead of hospital as contact for emergencies (-0.63), €50 co-payment (-0.48), 3h/day caregiver burden (-0.32), medium readmission risk (-0.24). Results were similar for informal care givers. **CONCLUSIONS:** A considerable proportion of patients and caregivers have a fixed preference for either admission or hospital-at-home, regardless of the specifics of the program. When choosing between hospital-at home programs, co-payments and the burden on informal caregivers are the principal attributes.

PRS53

FURTHER DEVELOPMENTS OF THE ASTHMA LIFE IMPACT SCALE (ALIS)

Crawford SR[1], McKenna S[2], Twiss J[1], Tammaru M[3], Oprandi NC[4]
[1]*Galen Research Ltd, Manchester, UK,* [2]*Galen Research Ltd, Manchester, UK, UK,* [3]*University of Tartu, Tartu, Estonia,* [4]*University of Verona, Verona, Italy*

OBJECTIVES: The Asthma Life Impact Scale (ALIS) is a disease-specific measure used to assess the quality of life of people with Asthma. It was developed in parallel in the UK and US and has proven to be acceptable to patients, to have good psychometric properties and to be unidimensional. The objective of this study was to adapt and validate the ALIS for use in Italy and Russia. **METHODS:** The dual panel methodology was used to translate the ALIS for both cultures. Patient interviews were conducted to test the new language versions to ensure their face and content validity. A test-retest postal survey was conducted in both countries to assess the psychometric properties of the new adaptations. **RESULTS:** The translation process proved straightforward. Cognitive debriefing interviews conducted in Italy (n=15) and Russia (n=9) indicated that patients found the new versions of the ALIS easy to complete and relevant. Validation data were available from postal surveys in Italy (n=61) and Russia (n=71). Both new versions of the ALIS had good internal consistency (0.92) and high test-retest correlation coefficients (Italian = 0.86; Russian = 0.94) indicating good reproducibility. The Russian ALIS showed strong correlations with a measure of fatigue (CAFS; 0.87) and sleep (CASIS; 0.85). The Italian ALIS had a moderate correlation with the Nottingham Health Profile Energy level scale (0.63). Both adaptations of the ALIS were able to distinguish between patients based on their self-rated general health and asthma severity. **CONCLUSIONS:** The ALIS was successfully adapted for use in Italy and Russia. The psychometric properties of these new adaptations matched those of the original UK and US versions. The new instruments represent valid and reliable tools for measuring QoL in international clinical trials and for use in routine clinical practice.

PRS54

TESTING OF A CONCEPTUAL MODEL OF ASTHMA IN ADOLESCENTS

Bright N[1], Maguire L[1], Arbuckle R[1], Tabberer M[2], Dale P[2]
[1]*Mapi Values, Bollington, Cheshire, UK,* [2]*GlaxoSmithKline, Uxbridge, Middlesex, UK*

OBJECTIVES: Conceptual Models (CM) are useful for characterising domains of Symptoms, Functioning and Treatment Satisfaction. Previously a Conceptual Model (CM) of asthma was developed and relevance to patients confirmed through qualitative interviews with 15 asthmatic adults. The aim of this research was to test the model in adolescents. **METHODS:** Twenty semi-structured interviews were conducted with asthmatic adolescents (aged 12-16) in the US. Cards were used to elicit feedback from the patients on their understanding and experience of different concepts included in the CM (symptoms and functioning/disability). Patients used the cards to rank the importance of symptoms and impacts. Treatment satisfaction was also discussed and the Asthma Control Test (ACT) completed. **RESULTS:** Based on the ACT 40% (8/20) of adolescents had poorly controlled asthma compared with 13% (2/15) of adults in the previous study. Most adolescents reported experiencing all four core symptoms of asthma; breathlessness (n=20), tight chest (n=19), cough (n=18) and wheeze (n=20). Additional symptoms reported by the adolescents were light-headedness (n=7), shaking (n=6), congestion (n=5), feeling as if about to pass out (n=2), vomiting (n=2) and an uncomfortable feeling in the ribcage (n=2). Breathlessness was the most important and bothersome symptom for both adolescents and adults. The functioning/disability concepts relevant to adolescents were the same as for adults. 'Spending time with friends/family' was the impact ranked as most important by adolescents (n=5). Understanding of terms and definitions was good for all core symptoms and impacts. The term 'rescue inhaler' was not familiar to a minority (3/12, 25%) of younger adolescents. **CONCLUSIONS:** Qualitative analysis of the interviews found evidence supporting all concepts in the CM. New symptoms reported by adolescents were distal symptoms experienced due to poorly controlled asthma or rescue medication overuse. No changes to the CM for asthma are needed for adolescents.

PRS55

FURTHER DEVELOPMENTS OF THE LIVING WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (LCOPD)

Crawford SR[1], McKenna S[2], Twiss J[1], Oprandi NC[3], Tammaru M[4]
[1]*Galen Research Ltd, Manchester, UK,* [2]*Galen Research Ltd, Manchester, UK, UK,* [3]*University of Verona, Verona, Italy,* [4]*University of Tartu, Tartu, Estonia*

OBJECTIVES: The Living with Chronic Obstructive Pulmonary Disease (LCOPD) scale is a disease-specific measure used to assess quality of life of people with COPD. The measure was developed in parallel in the UK and US and was shown to be highly acceptable to patients, unidimensional and have very good psychometric properties. The objective of this study was to adapt and validate the LCOPD for use in Italy, Spain and Russia. **METHODS:** Translated versions were produced using dual panel methodology. The translated versions were tested with patients to ensure face and content validity. Test-retest postal surveys were conducted to establish internal consistency, reproducibility and construct validity. **RESULTS:** The translation process proved successful for the new language versions. Cognitive debriefing interviews conducted in Italy (n=15), Spain (n=14) and Russia (n=8) indicated that patients found the new versions of the LCOPD acceptable and easy to comprehend. Validation data was generated from postal surveys in Italy (n=51), Spain (n=142) and Russia (n=69). All three versions showed good internal consistency ranging from 0.94-0.95, and good reproducibility was evident from the high test-retest correlation scores (Italian=0.96, Russian=0.94, Spanish=0.85). The Russian LCOPD had strong correlations with a measure of fatigue (CAFS; 0.87) and sleep (CASIS; 0.76). The Spanish LCOPD had a moderate correlation with the CAFS (0.66) and a strong correlation with the CASIS (0.75). The Italian LCOPD had strong correlations with three of the sub-scales of the Nottingham Health Profile (0.83) and with the NHP-D (0.86). The new adaptations of the LCOPD were all able to distinguish between patients based on their self-rated general health and COPD severity. **CONCLUSIONS:** The LCOPD was successfully adapted for use in Italy, Spain and Russia. These results were similar to those found for the original UK and US versions.

PRS56

ASSESSING PATIENT REPORT OF FUNCTION: CONTENT VALIDITY OF THE FUNCTIONAL PERFORMANCE INVENTORY-SHORT FORM (FPI-SF) IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE

Leidy N[1], McCormack J[1], Hamilton A[2], Becker K[3]
[1]*United BioSource Corporation, Bethesda, MD, USA,* [2]*Boehringer Ingelheim (Canada) Ltd., Burlington, ON, Canada,* [3]*Boehringer Ingelheim GmbH, Ingelheim/Rhein, Germany*

OBJECTIVES: The performance of daily activities is a major challenge for people with chronic obstructive pulmonary disease (COPD). The 65-item Functional Performance Inventory (FPI) was developed to quantify these difficulties in naturalistic studies and clinical trials. The instrument was based on an analytical framework of functional status and qualitative interviews; it was reduced to a 32-item short form (FPI-SF) through a systematic process of item reduction and testing and re-formatted for greater clarity and ease of use. This study assessed the content validity of the FPI-SF. **METHODS:** Qualitative cognitive interviews were performed with men and women with COPD recruited through pulmonary clinics in the United States. Interviews were conducted in-person by a trained interviewer using a semi-structured interview guide and continued to saturation. Qualitative data analyses included the following: 1) comprehensiveness; 2) clarity of instructions, items, and response options; 3) respondent interpretation of the instructions, items, and re-