THE CZECH BURDEN STUDY: SUBGROUP ANALYSIS (BURDEN AND QUALITY OF LIFE IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE EXACERBATION)

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OBJECTIVES: To estimate 6 months costs and quality of life (QoL) of patients with moderate to very severe COPD (GOLD criteria) who experienced a COPD exacerbation in comparison with control groups of similar COPD severity without exacerbation. METHODS: COPD in- and outpatients (Grade II = 28; III = 31; IV = 31) with exacerbation (3 months prior to exacerbation) and prospectively (3 month after exacerbation) and compared to controls (CO-groups) of similar disease severity but stable health (3 month retrospective assessment). Direct costs included hospitalization, outpatient visits, laboratory tests, imaging, medication and rehabilitation. Indirect costs included short and long term disability payments. All costs were converted to a period of 180 days; health care costs used 2008 prices from the payer’s perspective. A validated translation of the EQ5D was completed at inclusion day (all groups) and at final visit (EXA-groups). RESULTS: About 18% of grade-II and 31% of grade-IV exacerbations were hospitalized, resulting in increased costs with COPD severity (6-months median: Grade II = $346; III = $2159; IV = €3856; all p < 0.05). Median 6-months costs in CO-groups were lower, although increasing from moderate to very severe COPD (Grade II = €567; III = €1610; IV = €2064; all p < 0.05). Exacerbation accounted for 8% (grade-II) to 31% (grade-IV) of total monitored costs. Mean EQ5D utilities in the CO-groups and in the EXA-groups at final visit were comparable (moderate: 0.58 vs.0.636; severe: 0.623 vs. 0.591; very severe: 0.524 vs. 0.479; NS). Mean EQA-groups utilities at inclusion were significantly lower compared to final assessment (p < 0.001) and decreasing with COPD severity (moderate: 0.351 vs. 0.390; severe: 0.229 vs. 0.202; reflecting QoL impairment) COPD exacerbation and natural disease course. CONCLUSIONS: The BURDEN study confirmed for the Czech Republic a considerable economic burden of COPD. In accordance with international literature we found increased costs and decreased QoL for: 1) COPD exacerbation vs. control in stable state, and 2) COPD progression.

MEDICAL AND PRODUCTIVITY COSTS ATTRIBUTABLE TO OBESITY IN WORKING ADULTS WITH ASTHMA IN THE U.S.

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OBJECTIVES: To estimate annual medical and productivity costs attributable to obesity in working U.S. adults with asthma. METHODS: This study applied a cross sectional design using the 2003–2006 Medical Expenditure Panel Survey. Asthma patients (18–64 years old) were identified by self reported diagnosis or ICD-9-CM K04.0–9.9. Costs were estimated using the two-part model. Costs attributable to obesity were estimated by the differences between actual and expected costs, holding the distribution of covariates obtained from the normal and obese patients in the model. All costs were converted to 2008 U.S. dollars using price indices. RESULTS: Among a total of identified 4,317 working adults with asthma, prevalence of normal weight is 34%, while obese was 32%. The costs attributable to obesity were $2,384 (95% CI:2,232–2,536) for total medical treatment costs and $215 (95%CI $189–$241) for costs associated with productivity loss. The missed working days attributable to obesity were 2.4 days/year/patient (95%CI:2.1–2.7 days). The attributable costs to medical and productivity loss increased as patients became older or were female patients. CONCLUSIONS: Obese asthma patients have significantly higher costs associated with medical treatment and greater productivity loss compared to normal-weight asthma patients. Education aimed at weight control in asthma patients could result in a significant reduction in the economic burden of treating asthma patients and enhance productivity.

NEW PHARMAECONOMIC MODEL OF ASThma MAINTENANCE TREATMENT (OPTIMA) IN RUSSIA. TO TREAT OR NOT TO TREAT: MAINTENANCE TREATMENT VS. NO MAINTENANCE TREATMENT

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OBJECTIVES: To compare maintenance (using the fixed combination of Salmeterol + Fluticasone) and symptomatic (no maintenance) treatments of asthma with a developed transparent pharmacoeconomic model. METHODS: Lack of asthma control leads to unscheduled resources utilization and so growth of total treatment cost (direct and indirect). Algorithm of OPTIMA model calculation includes 4 steps: 1) Analysis of weighted average cost of maintenance medicines based on dosing, average prices in reimbursement, and dose distribution in assessing population, and 2) Assessment of cost associated with controlled and uncontrolled asthma based on number of unscheduled resources utilization (emergency service, outpatient visits, inpatient stays, day and work-off days) and their unit-cost (sources-current Russian legislation, RosStat data) as well as QoL. 3) Detection of frequency of controlled/uncontrolled asthma in arms based on clinical trials data. 4) Calculation of total cost in arms (cost of drug + % controlled + cost of controlled + % uncontrolled + cost of uncontrolled) and amount of saving. RESULTS: Weighted average cost of SAL/FP in Russia was 1672 Rub (~ 40 EUR) per month. Cost associated with controlled and uncontrolled asthma were 320 Rub and 62,753 Rub (~48 and 1,400) per patient per year, respectively. QoL scores were 0.75 and 0.69 respectively. Frequency of controlled asthma in the FP arm was 75% (QoL study) and so 25% patients were uncontrolled. Assumed frequency of controlled asthma using symptomatic treatment instead of SAL/FP was 5%. Total costs were 35,991 Rub and 59,632 Rub (~850 and €1,400) in maintenance and symptomatic arms, respectively; average QoL score was 69% and 50.3%. CONCLUSIONS: The model allows transparent comparisons of different asthma treatment approaches. Maintenance treatment with SAL/FP was superior (less cost and higher QoL) to symptomatic treatment.
prophylaxis cost far exceeding the direct financial benefit of preventing hospitalizations. Factors associated with lower ICERs included young age and the presence of multiple indications.

**PR518**

**COST-EFFECTIVENESS ANALYSIS OF FORMOTEROL ASSOCIATED TO BUDERONIDE FOR MAINTENANCE AND RELIEVER THERAPY (SYMBICORT SMART) VERSUS SALMETEROL ASSOCIATED TO FLUTICASONE IN THE TREATMENT OF MODERATE TO SEVERE PERSISTENT ASThma UNDER THE BRAZILIAN SOCIETAL PERSPECTIVE**

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**OBJECTIVES:** To develop a cost-effectiveness analysis of formoterol associated to budesonide for maintenance and reliever therapy (FB SMART) versus salmeterol associated do fluticasone (SF) in the treatment of patients with moderate to severe persistent asthma, under the Brazilian societal perspective. **METHODS:** A Markov model was developed to project costs and outcomes associated with disease progression of patients with moderate to severe persistent asthma receiving SMART therapy or SF in a one year time horizon. Weekly cycles were considered and the model structure consisted of four possible health states: disease control, use of oral corticoids (OC), hospitalization/emergency visit (H/EV) and death. The probabilities of having severe exacerbations (OC or H/EV) were extracted from the study by Kuna et al. All cause mortality rates were obtained from national epidemiological databases. Adverse events were not significantly different between comparators so were excluded from the model. Outcomes were expressed as quality adjusted life years (QALY) and only direct medical costs were included in the analysis. Resource use during hospitalization, was estimated based on an expert panel. Maximum prices to consumer were obtained for drugs, and procedure costs were extracted from the Brazilian Classification of Medical and Surgical Procedures (CPCM). **RESULTS:** In one year, the average number of severe exacerbations was 0.2436 in the SMART group and 0.3928 in the SF group, resulting in 0.1492 severe exacerbations avoided. Total cost for the SMART and SF groups were R$1823.56 and R$1417.49, respectively (incremental cost = R$406.07). The incremental cost-effectiveness ratio in 1 year was R$2721/SEA (US$1944 2005-PPP index USD1.0 = R$406.07). The variables that most influenced the results were the costs of SMART and SF therapy and the cost of hospitalization. **CONCLUSIONS:** SMART therapy reduces the risk of severe exacerbations when compared to SF in patients with moderate to severe persistent asthma, under the Brazilian societal perspective, at a reasonable incremental cost, being a valuable alternative for these patients.

**PR519**

**IS IT TIME FOR SMOKING CESSATION PRODUCTS TO BE REIMBURSABLE IN THAILAND?**

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**OBJECTIVES:** Currently, no smoking cessation product is listed on National Essential List of Essential Medicine in Thailand. This study aimed to evaluate the cost-effectiveness of non-nicotine smoking cessation products in Thailand from health care system perspective. **METHODS:** A Markov model was developed for smoking cessation on cohorts of 10,000 male smokers aged 40 who regularly smoked 10-20 cigarettes a day. An incremental cost-effectiveness ratio of varenicline, bupropion, and nortriptyline compared to self-quitting was estimated. Transition probabilities were obtained from literature reviews, while medical care costs and utility weights patterns were derived from a database of a Thai tertiary-care hospital and from the literature. The efficacy of all three products was obtained from a Bayesian meta-analysis. Costs of the medications were obtained from the Thai Drug and Medical Supply Information Center. Both costs and outcome were discounted at three percent. All costs were presented in 2008 Thai Baht. A series of sensitivity analysis including probabilistic sensitivity analysis, and cost-effectiveness acceptability curve were performed. **RESULTS:** In comparison to self-quitting, using a non-nicotine smoking cessation product results in cost-savings. Varenicline use results in the highest cost savings of 21,187 Baht or approximately US$6605 and life-years gain of 0.25 years. The use of nortriptyline and bupropion was shown to lead to similar magnitude of both life years saved and cost-savings. Nortriptyline and bupropion use had cost-savings of 11,506 Baht and 10,734 Baht, respectively. Probabilistic sensitivity analysis demonstrated that the probability of cost-saving from using nortriptyline, varenicline, and bupropion for smoking cessation was 99%, 85%, and 80%, respectively. **CONCLUSIONS:** From the perspective of the health care system, using any of the three products yields cost-savings and life-year gains. These findings may persuade Thai policy-makers to consider including these smoking cessation products on the National List of Essential Medicine.

**PR520**

**ECONOMIC EVALUATION OF THE IMPACT OF THE MEXICO CITY’S NON-SMOKERS HEALTH PROTECTION ACT**


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**OBJECTIVES:** To evaluate the economic impact of the Non-Smokers Health Protection Act, implemented April 3rd, 2008 in terms of direct employment, wages, income and expenses in restaurants, bars and night clubs, in Mexico City. **METHODS:** The main information source is the Monthly Services Survey, produced by Nacional Institute of Statistics and Geography. The monthly series begins in January 2005 and the last available observation is for March 2009. Natural logarithms of the dependent variables were constructed and differences-in-differences regression models were estimated by Ordinary Least Squares (OLS) to evaluate the impact using a control group formed by Nuevo León and Jalisco, states that had similar behaviour before the date of implementation. **RESULTS:** Differences-in-differences estimations with robust p-values in parenthesis for the effect of implementation in restaurants are: 0.144 (0.57) for direct employment; 0.78 (0.568) for wages; −0.050 (0.277) for income and −0.174 (0.09) for expenses. In the case of bars and night clubs: −0.004 (0.976), 0.019 (0.881), 0.025 (0.56) and −0.049 (0.552) for direct employment, wages, income and expenses, respectively. Coefficients are non significant statistically. **CONCLUSIONS:** With available data, we conclude that there is no statistical evidence at 95% confidence level that suggests that the implementation of Mexico City’s Non-Smokers Health Protection Act has had a negative economic effect in direct employment, wages, income and expenses in restaurants, bars and night clubs in Mexico City.

**PR521**

**COST-EFFECTIVENESS ANALYSIS OF XOLAIR® UNDER REAL LIFE CONDITIONS IN BELGIAN PATIENTS WITH SEVERE ALLERGIC ASTHMA**

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**OBJECTIVES:** To assess, in real life conditions, the costs, effects, and cost-effectiveness of Xolair® (omalizumab) as add-on therapy compared to conventional therapy in the treatment of Belgian patients with severe persistent allergic asthma inadequately controlled. **METHODS:** The same Markov model used for omalizumab initial reimbursement dossier was populated with data from a Belgian observational study, i.e. PERSIST study (n = 160), especially set up to address questions raised by the Belgian authorities for omalizumab re-evaluation. The model takes into account four health states and links effectiveness data, real life resource use, and utility data. Medical resources use (drug treatment, laboratory tests and procedures, physician consultations, emergency room visits, and hospitalisations) were collected in PERSIST and costed from the perspective of the health care payer (i.e. INAMI/RIZIV patient). EQ-SD data were also collected during the study and used in the Markov model. **RESULTS:** Over a lifetime time horizon, the expected average numbers of life years (LYs) and QALYs per patient, for conventional therapy are 18.33 and 9.80, respectively. For omalizumab, the respective figures are 22.19 and 12.54. Over a lifetime time horizon, the expected average costs per patient are €44,548 and €124,726 for conventional therapy and omalizumab as add-on, respectively. Hence, omalizumab ICERs are €20,777/LY gained and €29,187/QALY gained. This comparison is, however, not substantially different in the ICERs with the initial submission ICERs (i.e. €40,370/LY gained and €42,669/QALY gained). The sensitivity analyses performed show that results can somewhat vary according to the parameters changed. However, in all cases, the ICERs obtained with real life data are always markedly inferior to what was calculated in our initial submission. **CONCLUSIONS:** The methodology used to simulate the effect of Xolair® on data from a real life Belgian study confirms that omalizumab is cost-effective versus conventional therapy in the treatment of patients with severe persistent allergic asthma inadequately controlled.

**PR522**

**COST-EFFECTIVENESS ANALYSIS OF TIOTROPIUM IN THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) PATIENTS IN SPAIN**

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**OBJECTIVES:** The aim of this study is to analyze if tiotropium bromide is an efficient alternative respect to ipratropium bromide and standard therapy, in the management of chronic obstructive pulmonary disease (COPD) patients in Spain. **METHODS:** Efficiency of the different alternative options in COPD treatment was evaluated with a cost-effectiveness analysis. Tiotropium bromide was compared to ipratropium bromide and standard therapy by means of a cost-effectiveness analysis that estimates life years gained (LYG) with tiotropium respect to alternatives, by combining mortality associated to COPD exacerbations with rates of exacerbations taken from two meta-analysis of head to head clinical trials. The time horizon of the study was 13 years, the mean life expectancy in COPD patients included in the clinical trials with tiotropium. Uncertainty was studied by successive univariate sensitivity analysis of key parameters of the model and a probabilistic sensitivity analysis. All costs were expressed in €2008 and a 3% discount rate was applied to costs and effects. The analysis took the perspective of the Spanish National Health System (NHS). **RESULTS:** Incremental cost-effectiveness ratio (ICER) when treating COPD patients with tiotropium versus standard therapy was €2873/LY, and in patients treated with tiotropium versus ipratropium bromide was €4208/LY. Univarient sensitivity analysis showed that results where most sensitive to COPD severity and the future costs of surviving patients. **CONCLUSIONS:** Treating COPD patients with tiotropium is an efficient alternative respect ipratropium bromide or standard therapy for the Spanish NHS.