A PEG hydrogel sealant (PleuraSeal<sup>TM</sup>) is used as an adjunct to standard closure of pleural air leaks during lung resection surgery and has demonstrated shorter hospitalizations (1.7 days fewer) and more rapid removal of chest tubes in clinical studies when compared with standard of care (e.g., staples and sutures alone). Our study was designed to estimate the potential cost offsets for using PleuraSeal<sup>TM</sup> compared with standard of care in 100 hypothetical patients from a UK hospital who had an air leak after lung resection surgery using the cost offset from shorter hospital stay balanced against the cost for PleuraSeal<sup>TM</sup>. METHODS: We assumed the cost for PleuraSeal<sup>TM</sup> to be £160 per treatment applied to all 100 hypothetical patients compared with £17 per patient when compared to standard of care as patients who had air leaks stayed in hospital an average of 1.7 days longer than those without air leaks. CONCLUSIONS: The cost for PleuraSeal<sup>TM</sup> is a compelling option for hospitals who perform lung resection surgeries as the cost of the treatment is completely offset by the reduction in air leaks and subsequent hospital stay.

**ALBUTEROL AND LEVALBUTEROL USE AND SPENDING IN MEDICARE BENEFICIARIES WITH COPD**

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**OBJECTIVES:** There is inconclusive evidence on the advantages of branded levalbuterol over generic albuterol. This study is the first to evaluate the use and spending of these two short-acting beta agonists in a nationally representative sample of Medicare beneficiaries with COPD who enrolled in Medicare Part D. The study also examines patient characteristics associated with levalbuterol use and compares the use of other Medicar Part B and D covered COPD medications among albuterol and levalbuterol users. METHODS: Data were obtained from the 2005–2006 5% Medicare files linked to the 2005 Medicare Part D files. The sample consisted of all fee-for-service beneficiaries with COPD enrolled in stand-alone Part B and D plans in 2006. Patient characteristics and other COPD medication use were compared across albuterol-only users, levalbuterol-only users, and users of both medications. Multinomial logistic regressions identified the independent factors associated with levalbuterol use. RESULTS: There were 5.5 times more levalbuterol users than albuterol users; yet total spending on levalbuterol was £169 million whereas on albuterol was £50 million in 2006. Levalbuterol-only users were more likely to be older, sicker, and reside in the South than albuterol-only users. Part B-covered rhDNase fortuitously were the most frequently switched among albuterol-only users whereas albuterol-only users were more likely to use inhalers under Part D. CONCLUSIONS: Our findings on the striking differences between levalbuterol and albuterol users in terms of spending, patient characteristics, geographic region, and drug formulation/device type call for further investigations into these issues as well as comparative effectiveness and cost-effectiveness studies of these agents.

**COST-UTILITY ANALYSIS OF TIOTROPium, MEDICINE FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASES (COPD), IN JAPAN**

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**OBJECTIVES:** To perform a cost-utility analysis to estimate the potential cost offsets for using tiotropium compared with standard of care in 100 hypothetical patients from a UK hospital who had an air leak after lung resection surgery using the cost offset from shorter hospital stay balanced against the cost for PleuraSeal<sup>TM</sup>. METHODS: We assumed the cost for PleuraSeal<sup>TM</sup> to be £160 per treatment applied to all 100 hypothetical patients compared with £17 per patient when compared to standard of care as patients who had air leaks stayed in hospital an average of 1.7 days longer than those without air leaks. CONCLUSIONS: The cost for PleuraSeal<sup>TM</sup> is a compelling option for hospitals who perform lung resection surgeries as the cost of the treatment is completely offset by the reduction in air leaks and subsequent hospital stay.

**BENEFICIARIES WITH COPD**

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**OBJECTIVES:** Approximately 4.5 million Canadians, or 16.6% of the total population, smoke. Although the prevalence of smoking has shown a significantly decreasing trend, nicotine dependence remains a major public health issue. A number of pharmacological treatments are available to help smokers quit such as nicotine replacement therapies, bupropion and varenicline. The objective of this study was to evaluate the incremental cost-utility ratio of pharmacological anti-smoking treatments. METHODS: A Markov model based on the Benesco Simulation model (the Benefits of Smoking Cessation on Outcomes) was developed to determine the costs and QALYs associated with the nicotine replacement therapies, bupropion and varenicline. This cost utility analysis was performed over a lifetime horizon and from a health care system perspective. The model considers the health status of smokers, recent non-smokers and long-term non-smokers; the adverse health outcomes of smoking (asthma, chronic obstructive pulmonary disease [COPD], coronary heart disease, stroke and lung cancer); and deaths from all causes and from smoking. The model also considers smoking cessation probabilities associated with anti-smoking treatments, probabilities of resuming, probabilities of complications attributable to smoking, and probabilities of death. The costs considered are the costs of anti-smoking treatments according to recommended doses and amounts reimbursed by the Régie de l’assurance maladie du Québec. RESULTS: Nicotine patches, with higher costs and less QALYs, are dominated by bupropion and varenicline. Varenicline is also dominated by bupropion. Varenicline is the most effective of the anti-smoking treatments studied, albeit more costly than nicotine gum and bupropion. The incremental cost-utility ratios for varenicline versus nicotine gum and bupropion are respectively $825 and $1,235 per QALY. CONCLUSIONS: Results show that varenicline is the most effective option of the currently available pharmacological anti-smoking treatments, with a very acceptable cost-utility ratio.

**COST-UTILITY ANALYSIS OF ANTI-SMOKING TREATMENTS IN THE UNITED STATES**

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**OBJECTIVES:** To assess cost effectiveness of Natalizumab, Glatiramer Acetate (GA) and Interferon-β in treating patients diagnosed with relapsing-remitting multiple sclerosis (RRMS) from a United States (US) patient’s perspective. METHODS: A 30-year Markov model was developed with 6 health states transitions through the Kurtzke Expanded Disability Status Scale (EDSS). Patient health status was defined as mild, moderate, or severe when their EDSS score was 0.0–3.5, 4.0–6.0, 6.5–9.5, respectively. The model was parameterized with data from an extensive literature review and was adjusted where necessary to 2008 values. Transition probabilities included patients initial distribution based on EDSS score, relapse rate, mortality rate, and progression rate. The total cost included direct (inpatient and outpatient admissions, office visits to physicians, examinations, medication, medical devices, alterations to the home and informal care from family) and indirect costs (productivity losses, and early retirement). The utility considered was Quality Adjusted Life-Year (QALY). Sensitivity analyses were conducted on all the transition probabilities at a range of ±25% to check the robustness of the result. RESULTS: Based on the result of the 30-year Markov Model, patients treated with Natalizumab spend $1,104,773 to gain 10.47 QALYs, while patients treated with Interferon-β spend $880,199 to obtain 9.88 QALYs and for those patients treated with GA have to spend $907,854 to yield 7.07 QALYs, which means patients treated with Natalizumab, Interferon-β or GA have to spend $105,417, $89,088, $128,409 respectively to gain one QALY. The model suggests that Interferon-β is the most cost-effective DMT agent, with an ICER of $380,634 per QALY compared with Natalizumab. Compared with GA, the ICER for Interferon-β per QALY was $9,841. Sensitivity analysis showed that the results were robust to changes in all parameters. CONCLUSIONS: In our study, Interferon-β proved to be more cost effective than both Natalizumab and GA for RRMS patients.

**SMOKING AND WORKPLACE CONSEQUENCES: EVALUATION IN FRANCE**

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**OBJECTIVES:** Tobacco is the primary cause of preventable death in France (66,000 deaths/year). Places of work and business are no exception. The objective of this study is to gain a better understanding of smoking and its consequences at work, thereby permitting new data to be obtained which will encourage businesses to take smoking into account. METHODS: In June 2009, the CSASantéInstitute composed a representative sample of the active French population according to the quota method. A total of 1590 people were interviewed. RESULTS: Of the total active population, there is no significant difference according to business size relative to the prevalence of smokers. The relationship between smoking and the number of breaks is linear (1 break for 2.5 cigarettes smoked/day). Smokers are subject to even more criticism (because of their break) by their colleagues and their hierarchy if they are heavy smokers. Smokers of more than 1 pack a day tend to be accompanied for their breaks. Smokers have more disrupted
employment than non-smokers or ex-smokers: 14.26% of subjects acknowledge having had their employment disrupted within the past 6 months. The differences noted between the “smokers”, “ex-smoker” and “non-smoker” populations are statistically significant (p < 0.001) with prevalence of disrupted employment respectively of 19%, 15.25% and 11.57% (p < 0.01). It is also noted that the prevalence of smoking during work hours is significantly more important when the hierarchical superior smokes, 64.4% smoke during work hours if the hierarchical superior smokes, vs. 17.1% if the hierarchical superior does not smoke (p < 0.004). CONCLUSIONS: In a population representative of persons at work on French soil, this study confirms the data collected abroad and in certain businesses in France. Therefore, the justification for taking smoking into account at the work place is reinforced by its health consequences as well as its direct consequences on the work produced.

PR332 RELATIONSHIP OF COST-SHARING LEVELS TO ADHERENCE WITH DUAL-CONTROLLER THERAPY AMONG ASTHMA PATIENTS

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OBJECTIVES: To analyze the effect of cost-sharing levels and other co-variates on adherence to asthma controller therapy among patients with moderate persistent asthma. METHODS: Data for this study came from a large administrative claims database (MarketScan). The selection criteria for this study included at least one asthma-related outpatient claim (ICD-9-CM 493.XX). Asthma patients on dual controller therapy (ICS and LABA or ICS and LTRA) were identified and the initial date of LABA or LTRA prescription served as the index date. Patients were to be continuously enrolled for at least six months prior to and during the observation period. All patients met the study criteria. Of these patients, 898 (62.1%) were initiated on ICS/LABA, and 349 (37.9%) were initiated on ICS/LTRA. The average combined adherence to controller regimen was 0.63 (median = 0.63) for the entire study population. The odds of having increased adherence (MPR above the median) decreased significantly with the increase in cost-sharing levels. Compared with patients having $0–10 cost-sharing level, patients having $16–30 (odds ratio [OR] = 0.449, 95% CI = 0.312–0.661), $31–45 (OR = 0.236, 95% CI = 0.168–0.338) and $46 and more (OR = 0.113, 95% CI = 0.084–0.157) had lower odds of having appropriate adherence. Type of insurance plan, geographical region, and type of controller therapy were also significantly associated with adherence. CONCLUSIONS: Even though the need to be adherent is greater among patients on dual-controller therapy, cost-sharing levels played an important role in level of adherence. The study also found the type of controller medication to be associated with the adherence to the therapy.

PR333 TRANSLATING THE EXACT: ENSURING CONCEPTUAL EQUIVALENCE ACROSS MULTIPLE CULTURES

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OBJECTIVES: Translation and linguistic validation of patient reported outcomes (PRO) measures is an essential component of research methodology in preparation for multinational clinical trials. The EXAcerbations of Chronic Pulmonary Disease Tool (EXACT) was designed to be a patient reported measure (PRM) of exacerbations of chronic obstructive pulmonary disease (COPD), including chronic bronchitis. The EXACT is 14-item daily diary designed to be administered on an electronic handheld device (e.g. personal digital assistant (PDA)). The objective of this work was to translate and linguistically validate the EXACT for use in 17 countries: Australia, Austria, Belgium, Bulgaria, Canada, Denmark, Hungary, Japan, Korea, The Netherlands, Peru, Philippines, Poland, Romania, South Africa, Taiwan and UK. METHODS: The EXACT was translated according to industry standard methodology, including detailed item definitions based on qualitative work conducted during instrument development. Five patients per country completed the respective translated questionnaire and participated in a cognitive interview. Interviews were conducted using a standardized guide to assess the understandability, cultural relevance, and appropriateness of wording of the translations. Qualitative analyses were performed to ensure that the content validity of the EXACT was maintained and equivalent across language versions. RESULTS: The study sample consisted of 90 patients with COPD (57.7% male). Mean age was 63 years. The sample consisted of patients who speak 14 languages collectively. All EXACT translations were well understood and proved relevant to the patients in this sample. Of interest, terms such as, “chest feel tight”, and “short of breath” were understood and described similarly by participants across countries. CONCLUSIONS: The results indicate the EXACT translations were conceptually equivalent to the English source version and easily understood by the target population for all 17 countries. We consider these translations acceptable for PRO assessment in international research and clinical trials, bringing the total number of validated EXACT translations to 25.

PR334 EVALUATING PEOPLE’S PREFERENCES FOR PREVENTIVE TREATMENT OF LATENT TUBERCULOSIS INFECTION USING A DISCRETE CHOICE EXPERIMENT

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OBJECTIVES: This study aimed to quantify the preferences of people with latent tuberculosis infection (LTBI) when making decisions on whether to accept preventive treatment with isoniazid and to understand the trade-off nature of their decision-making. METHODS: English-speaking adults with LTBI were recruited from the tuberculosis (TB) clinic at British Columbia Centre for Disease Control. A custom-designed discrete choice experiment (DCE) measured preferences for 6 attributes of preventive treatment decision-making. A conditional logit model was performed to estimate respondents’ preferences. RESULTS: Among the 152 participants, 142 (93.4%) with valid DCE responses were included for data analyses. Their average age of 1,000 COPD patients, increasing PDC by 5 percentage points would save $300,000 per year, mostly from reduced hospital visits.

PR331 RELATIONSHIP BETWEEN DAILY DOSING FREQUENCY, COMPLIANCE, HEALTH CARE RESOURCE USE, AND COSTS: EVIDENCE FROM THE TREATMENT OF CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD)

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OBJECTIVES: To assess the relationship between the daily dosing frequency (DDF) of COPD pharmacotherapies and treatment compliance; to estimate the effect of compliance on health care resource utilization (HCRU) and costs; and METHODS: COPD patients were identified using a health insurance claims database covering 8 million lives (1999-2006). Patients were stratified based on the recommended DDF (QD, BID, TID, QID) of their first COPD drug claim post COPD diagnosis. Compliance was measured using proportion of days covered (PDC). HCRU outcomes included inpatient days and medical visits (inpatient, outpatient, and emergency room). A multivariate regression model assessed the relationship between compliance and one-year HCRU controlling for demographics, comorbidities, and baseline resource use. Unit health care costs were obtained from the 2005 Medical Expenditure Panel Survey data and adjusted to 2008 dollars. Total costs were modeled by multiplying unit costs by the observed HCRU. RESULTS: Sample sizes ranged from 3,678 (QD) to 23,013 (BID). Compliance was strongly correlated with DDF: PDC over one year for QD, BID, TID, and QID patients was 43%, 37%, 30%, and 23%, respectively (all p < 0.001 vs QD). Multivariate analysis showed that one-year compliance was correlated with 0.48 in 2000. In 2000, compliance decisions on whether to accept preventive treatment with isoniazid and to understand the trade-off nature of their decision-making. METHODS: English-speaking adults with LTBI were recruited from the tuberculosis (TB) clinic at British Columbia Centre for Disease Control. A custom-designed discrete choice experiment (DCE) measured preferences for 6 attributes of preventive treatment decision-making. A conditional logit model was performed to estimate respondents’ preferences. RESULTS: Among the 152 participants, 142 (93.4%) with valid DCE responses were included for data analyses. Their average age of 1,000 COPD patients, increasing PDC by 5 percentage points would save $300,000 per year, mostly from reduced hospital visits.