

icy can be implemented only if decision-makers have the access to analytical tools to address different policy scenarios. It requires initial investment, which pays off in better decisions.

### PDB83

## THE EPIDEMIOLOGY AND BURDEN OF OBESITY AND DIABETES IN FRANCE: A METHODOLOGICAL COMPARISON

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OBJECTIVES: The aim of the current study is to utilize two different methodologies to estimate the prevalence and burden of type 2 diabetes (T2D) and obesity among the adult population in France. METHODS: Two separate representative data sources were used for the adult French population. Data from the French respondents of the EU National Health and Wellness Survey (NHWS) (N=15,051) and the OBEPI survey (N=25,286) were used. The NHWS is an internet-based annual survey and the OBEPI is a mailed survey conducted every three years, validated by the  $French \ authorities. \ Prevalence \ information \ for \ T2D, comorbid \ treatments, \ and \ BMI$ were analyzed using both data sources. The humanistic and economic burden of T2D was analyzed only from the NHWS data. RESULTS: From NHWS, 44.3% of respondents from France were male and the average age was 45.1 years (SD=15.5). From OBEPI, 47.8% were male and the average age was 48.2 years (SD=17.8). A total of 30.5% (OBEPI=31.9%) and 15.6% (OBEPI=14.5%) of the French population were estimated to be overweight and obese, respectively. A total of 4.4% (from NHWS) and 4.8% (from OBEPI) of the adult French population reported suffering from T2D. Among these patients, 15.1% and 80.5% were taking an insulin and oral treatment, respectively (12.4% by OHA+insulin and 76.0% by OHA only as estimated by OBEPI). From NHWS, a significant burden was observed among patients with T2D as they reported significantly lower levels physical quality of life (using the SF-12v2; 42.6 vs. 50.1, p<.05) and significantly greater work impairment (26.7% vs. 18.2%, p<.05) and physician visits (8.7 vs. 5.5, p<.05). CONCLUSIONS: Both internet and mailed survey methodologies provided consistent prevalence estimates of diabetes and obesity among the French population. Further, despite the high prevalence of treatment, significant effects are observed on health outcomes among T2D patients, highlighting the unmet need.

## Respiratory-Related Disorders - Clinical Outcomes Studies

## PRS1

## COST-EFFECTIVENESS OF VARENICLINE VERSUS EXISTING SMOKING CESSATION STRATEGIES IN BRAZIL FROM THE PUBLIC PERSPECTIVE, USING THE BENESCO MODEL

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OBJECTIVES: According to DATASUS, from 1996 to 2005, there were more than 1 million hospitalizations related to smoking, with total costs sum of half billion dollars. The aim of this study was to assess the cost-effectiveness of varenicline compared to other existing strategies for smoking cessation in an adult population cohort from the public payer's perspective. METHODS: The Benefits of Smoking Cessation on Outcomes (BENESCO) simulation model was used for an 18 years of age and older cohort of 557,881 smokers, within a lifetime time horizon. Smoking cessation therapies in comparison were: varenicline (0.5–2 mg/day), bupropion (300  $\,$ mg/day), nicotine replacement therapy (NRT) (5-10 mg/day), and unaided cessation. Relapse rates were considered as 6.3% for the first 5 years after cessation, 2% for years 6 to 10 and 1% for subsequent years. Effectiveness measure was Life-Year gained (LYG). Smoking and smoking-related heath condition's prevalence, resource use and costs data were obtained from DATASUS, INCA (National Cancer Institute), INCOR (Heart Institute) and DECIT (Science and Technology Department of Brazil). The model used a 5% discount rate for health outcomes and costs were expressed in 2010 USD. **RESULTS:** LYG for varenicline was 7310 compared to 7295 from bupropion, 7294 from nicotine replacement therapy and 7273 for untreated treatment. Compared to untreated patients, varenicline reduced smoking-related morbidity by 10,757 events, prevented 8,612 early deaths due to smoking related events, representing savings for US\$139.602.241,20 from heathcare expenses. The net average cost per additional quitter showed that varenicline was cost-saving against bupropion (- USD 1.122,00) and nicotine replacement therapy (- US\$ 46.184,40). CONCLUSIONS: Smoking cessation therapy with varenicline is costsaving for Brazil. These results could help to reduce the tobacco related disease burden while agreeing with cost-containment policies.

# THE ROLE OF RX DATA IN COMPARATIVE EFFECTIVENESS RESEARCH

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OBJECTIVES: To demonstrate Rx data application in relation to comparative effectiveness of inhaled corticosteroids (ICS) through evaluation of the rate of adherence to drug therapy and consumption of rescue medications in respiratory impaired patients. METHODS: Participants: A total of 533,382 patients age 18 or older who filled a prescription for ICS drugs. Setting: More than 12,153 community pharmacies nationwide. Data were from computerized pharmacy records. Design: The persistency analysis included prescription data for ICS dispensed during a 4-month period. Patient prescription activity was followed for 360 days. Patients were monitored for consumption of short acting beta agonist (SABA) medication in combination with their index ICS for 360 days from their ICS index fill date. An average SABA consumption in days for each index ICS drug was calculated. RESULTS: Persistence with ICS is generally poor; about 60% to 78% of patients drop off therapy within the first 30 days of therapy. Fluticasone/salmeterol (F/S) combination shows the best persistence and budesonide the worst persistence. Children were more persistent with mometasone whereas patients 19-60 and 60+ were more persistent with F/S. Budesonide and triamcinolone had the worst persistence with all age groups. The same results were seen in patients with multiple co-morbidities. Persistency with ICS across different co-morbid condition was consistent. On average 67% to 91% of ICS users took a SABA concomitantly. Budesonide (N=69,432) patients on average used fewer days of SABA therapy (higher control), whereas budesonide/formeterol combination (N=25,763) patients used more days of SABA therapy (lower control). **CONCLUSIONS:** Rx data can be used to compare effectiveness of drugs in a class across different population segments. Our analysis showed that different ICSs have different effectiveness, as indicated by the rate of adherence to therapy and use of rescue medication, in different individuals.

## THE EFFECT OF AAT REPLACEMENT THERAPY ON PATIENT LENGTH AND **OUALITY OF LIFE - A MARKOV MODEL**

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OBJECTIVES: To model the outcomes associated with alpha-1-antitrypsin deficiency (AATD) related emphysema, an orphan disease, through the use of a Markov cohort model. METHODS: A simulated cohort of 773 patients (the number predicted patients in the UK) were transitioned between seven health states: mild, moderate, severe, very severe, lung transplantation, post lung transplantation and death, according to transition probabilities calculated from pooled randomised controlled trials. Computed tomography (CT) is accepted to be a more sensitive and correct measure of progression of disease in AATD-related emphysema, whereas FEV1 is a more recognised measure of lung function for clinical management of pulmonary disorders. Thus to model disease progression, CT decline from the randomised trials was converted to FEV1 decline through two different mapping algorithms, and transition probabilities calculated accordingly. Health-Related Quality of Life decreases as disease progresses, with utility values taken from the literature. At the stage where FEV1 % predicted fell below an eligible threshold, patients underwent lung transplantation. A predefined limitation on the number of lungs available reflected the competition for lung transplantation in the healthcare system. The model outputs include Life Years, QALYs, Lung transplantations, and disease specific mortality. All values were discounted at 3.5%. RESULTS: AAT replacement therapy resulted in an increase of 0.32 life years (6.93 vs. 6.61), with an estimated gain of 0.28 QALYs per patient (4.64 vs. 4.27) over best supportive care. For a cohort of 773 patients over a lifetime horizon, 19 AAT deficiency deaths and 6 lung transplantations were avoided when patients were treated with AAT compared to best standard care. **CONCLUSIONS:** Treatment with AAT slows decline in lung function and delays death associated with AATD. By slowing lung function decline, patients experience improved health related quality of life, while fewer lung transplantations are required, increasing the number of donor organs available for use in other diseases.

## EFFECTIVENESS OF A MULTIFACTORIAL INTERVENTION TO IMPROVE ADHERENCE IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE (COPD) ICEPOC STUDY

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OBJECTIVES: To assess the effectiveness on treatment adherence of a multifactorial intervention in patients with COPD. METHODS: Design: Randomized Control Trial (ISRCTN 15106246) Patients: 146 subjects randomly allocated (random blocks of 4 patients) in two groups (intervention group: IG, control group: CG). Intervention components: 1) Motivational aspects related with adherence: beliefs-behaviour about COPD (group and individual interviews); 2) Cognitive aspects: information about illness; and 3) Skills: inhaling techniques training. Follow-up: 1 year, 5 visits/ group: 1) V0 random allocation, all variables were measured; 2) V0C adherence was measured; 3) V1-V2 (3-6 moths after start/intervention) adherence and variable changes were measured; and 4) V3 (one year after start/intervention) all variables were measured. Primary Outcome: adherence (doses recount); Secondary Outcomes: functional status (spirometry), quality of life (Saint George Respiratory Questionnaire-SGRQ); Independent variables: age, sex, educational level, comorbidity, COPD severity stage (SEPAR guidelines), prescribed medication. RESULTS: Predominace of males (91.8%), mean age 69.01 years (CI95%, 67.58-70.44); low cultural level (78.1%), 32.2% current smokers (29.36 cigarettes/day [CI 95%, 26.03-32.7]) overweight (Body Mass Index 30.78 kg/m2 [CI 95%, 28.78-32.78]), 81.2% mild-moderate severity stage, predominance of obstructive respiratory pattern; FEV1 (mean)=68.76% (CI 95%, 65.23-72.29), 0.87 exacerbations/year [CI95%, 0.68-1.06]. Pharmacological treatment: inhaled-anticholinergic (77.4%); inhaled-beta2-adrenérgic (80.1%); inhaled-corticosteroids (70.5%); xantins (8.2%); oxygen therapy (4.8%); oral-corticosteroids (0.7%); mucolytics (11.6%). All these measurements were similar in both groups. Adherence was 41% (41.2CG/40.8IG). 93 patients (63.7%) completed follow-up. Adherence in follow-up V1=61.8% (58.9CG/65.2IG), V2=66.3% (63.2CG/71.1IG), V3=56.8% (43.1CG/72.7IG). Significative differences between study groups (p=0.004). NNT for intervention:6,8 Multivariate analysis (Adherence): (specificity = 87.5%, sensibility = 60.4%: intervention [OR=6.066 (IC95%,