

tions. Extrapolating to national data, it is estimated that more than €14 billion were paid for AEDs in off-label use (more than €13 billion paid by the NHS).

#### PND8

##### PREVALENCE AND INCIDENCE RATES OF MULTIPLE SCLEROSIS IN THE UNITED STATES

Baser O<sup>1</sup>, Wang L<sup>2</sup>, Li T<sup>3</sup>, Shu Z<sup>3</sup>, Xie L<sup>4</sup>

<sup>1</sup>STATinMED Research/The University of Michigan, Ann Arbor, MI, USA, <sup>2</sup>STATinMED Research, Dallas, TX, USA, <sup>3</sup>STATinMED (Beijing) International Healthcare Technology Assessment Co., Ltd., Beijing, China, <sup>4</sup>STATinMED Research, Ann Arbor, MI, USA

**OBJECTIVES:** Multiple sclerosis (MS) is a chronic inflammatory disease with 12,000 new diagnoses per year in the United States. Higher latitude is associated with higher MS prevalence rates, and the female-to-male ratio in MS incidence has been estimated at 2:3 in 2000. This study aims to estimate the prevalence and incidence rate of MS in the United States. **METHODS:** Patients with an MS diagnosis (International Classification of Diseases Ninth Revision Clinical Modification [ICD-9-CM] code: 340.XX) between January 2006 and December 2010 were identified from a large U.S. claims database. Prevalence rates from 2006 to 2010 were calculated by dividing the number of MS patients by the total number of health plan enrollees in each year. The 2010 incidence rate was calculated by dividing the number of patients with a new MS diagnosis in 2010 by the total number of enrollees in 2010. **RESULTS:** The prevalence rate remained stable at 0.16% from 2006 to 2008, and then increased in 2009 (0.17%) and again in 2010 (0.19%). In 2010, MS prevalence in women (0.26%) was more than twice the rate than that of the male population (0.09%). To examine regional differences, prevalence rate was also calculated for each U.S. state. Regional prevalence rates ranged from 0.11% (Arkansas) to 0.29% (Rhode Island). The estimated incidence rate for 2010 was 0.03% for the overall population, 0.05% for female, and 0.02% for male patients. Incident cases had an average age of 49 years, and were more likely to suffer from comorbid conditions, such as disturbance of skin sensation, fatigue, and hypertension. Incidence rates by state ranged from 0.01% (Maine) to 0.08% (Michigan). **CONCLUSIONS:** This study confirms that MS prevalence and incidence rates are higher in female patients, and in regions farther away from the equator.

#### PND9

##### FREQUENCY AND IMPACT OF RELAPSES IN GERMAN PATIENTS WITH MULTIPLE SCLEROSIS BASED ON A LONGITUDINAL POPULATION-BASED STUDY

Schmidt J<sup>1</sup>, Dippel FW<sup>2</sup>, Kuehne S<sup>3</sup>, Holz B<sup>4</sup>, Larisch K<sup>5</sup>

<sup>1</sup>TU München, Garching, Germany, <sup>2</sup>Sanofi Deutschland GmbH, Berlin, Germany, <sup>3</sup>Sanofi-Aventis Deutschland GmbH, Berlin, Germany, <sup>4</sup>Genzyme GmbH, Neu Isenburg, Germany, <sup>5</sup>Gesundheitsforen Leipzig GmbH, Büro München, München, Germany

**OBJECTIVES:** One important aspect for patients suffering from multiple sclerosis (MS) is the frequency and severity of relapses that lead to a significant increase in symptoms and an aggravation of health related quality of life. In this study, data of about 3,000 MS patients have been analysed over a five year period in order to identify the number of relapses and the events that may follow a relapse. **METHODS:** Information was taken from 2006 to 2010 German claims data. To identify a relapse, several indicators such as hospitalisations, specific relapse medication and outpatient consultations have been investigated. **RESULTS:** The results show that the identification of relapses can be achieved by including inpatient, outpatient and relapse medication data. Relapses were found for 47% of all MS patients. Among those receiving MS medication, 67% suffered from relapses while only 32% of the patients without medication were affected. This may indicate that the proportion of patients having a higher risk of relapses is usually under MS-treatment. Most patients with relapses (64%) did not show more than three relapses within five years. The events following a relapse were classified by the number of hospitalisations (14% within one month after the relapse), transitions from basic to escalating MS medication (3% within one quarter after the relapse) or changes of disease modifying drug (3% within one quarter after the relapse). Changes of basic MS medication are not necessarily related to relapses, while changes from basic to escalating MS medication are often observed after such an event. **CONCLUSIONS:** Patients with high frequencies of relapses are treated with disease modifying drugs more often than other patients. Most of the MS patients do not suffer from relapses within the observation period of five years, with a small group of patients suffering from numerous relapses.

#### PND10

##### FASTER COGNITIVE DECLINE IS ASSOCIATED WITH DECREASING SURVIVAL IN PATIENTS WITH ALZHEIMER'S DISEASE

van Sanden S<sup>1</sup>, Diels J<sup>2</sup>, Gaudig M<sup>3</sup>, Spencer M<sup>4</sup>, Thompson G<sup>5</sup>, Arrighi HM<sup>6</sup>

<sup>1</sup>EMEA HEMAR Analytics, Janssen EMEA, Beerse, Belgium, <sup>2</sup>Janssen Pharmaceutica, Beerse, Belgium, <sup>3</sup>Janssen Alzheimer Immunotherapy, Dublin, Ireland, <sup>4</sup>Janssen-Cilag Limited, High Wycombe, Bucks, UK, <sup>5</sup>Janssen-Cilag Ltd., High Wycombe, UK, <sup>6</sup>Janssen Alzheimer Immunotherapy, San Francisco, CA, USA

**OBJECTIVES:** To explore the impact of severity and rate of decline of cognitive impairment on mortality within Alzheimer's disease (AD) patients. **METHODS:** Data on AD patients were from CERAD (Consortium to Establish a Registry for Alzheimer's Disease), a US multicenter, longitudinal study. Patient demographics, cardiovascular and other co-morbidities, activities of daily living (ADL), cognitive impairment measured by the Mini-Mental State Examination (MMSE) and Clinical Dementia Rating (CDR), and survival status were obtained at study entry (baseline), and at annual follow-up visits. Study survival time was modelled as a function of patient baseline demographics, cognitive impairment at entry and its decline over time using parametric survival models and semi-parametric Cox proportional hazard model (PH), with decline of cognitive impairment as a time-dependent covariate. **RESULTS:** 1010 patients with non-missing survival data were included in

the analysis. At baseline, men, age and cognitive impairment significantly increased the mortality risk ( $p < 0.001$  for all). Additionally, patients progressing to a more severe stage of cognition over time had significantly higher mortality risk ( $p < 0.001$ ), with a hazard ratio for CDR change over time versus baseline as a time dependent covariate of 1.35 [95% CI: 1.21-1.51]. CDR and MMSE scores were highly correlated; results based on models using either CDR or MMSE were mostly consistent. Results were confirmed by sensitivity analyses with varying modelling assumptions. **CONCLUSIONS:** Severity and rate of decline of cognitive impairment are both strong predictors of survival in AD, additional to the usual demographic and clinical patient characteristics. These findings suggest that treatments delaying the progression of AD patients to more severe stages of cognitive impairment might positively impact overall survival.

#### PND11

##### ESTIMATING SURVIVAL-BENEFIT OF NEW THERAPEUTIC INTERVENTIONS IN CYSTIC FIBROSIS PATIENTS IN GERMANY, FRANCE, UK AND IRELAND

Becker CC, Kim M, Johnson C  
Vertex Pharmaceuticals, Cambridge, MA, USA

**OBJECTIVES:** Cystic fibrosis (CF), the most common lethal genetic disease in Caucasians, causes a high burden of disease. Median age at death is in the late 20s with the most common mode of death being respiratory failure. Treatment with ivacaftor, a CF transmembrane conductance regulator (CFTR) protein potentiator, was generally safe and improved risk-factors for mortality in CF, including pulmonary function, weight and pulmonary exacerbations. Since controlled clinical trials cannot directly demonstrate survival benefits, we estimated the potential for survival benefit from drug therapies based on similar, observed short-term changes to risk factors known to impact survival in CF. **METHODS:** Survival information for CF patients in Germany, France, the UK, and Ireland was obtained from national registries and individually fitted to a Weibull function. From these survival curves the hazard function for an average CF patient was calculated as a function of age. The impact to the hazard function from improvements in risk factors (FEV1, weight-for-age z-score, pancreatic sufficiency, diabetes, *Staphylococcus aureus*, *Burkholderia cepacia*, and annual number of pulmonary exacerbations) was estimated using previously published Cox proportional hazards model for CF mortality. **RESULTS:** For each country, a survival function was developed taking into account current average mortality rates and estimated long-term changes to risk factors. Sensitivity analysis suggest that it is possible for drugs that improve clinical outcomes in CF, including pulmonary function, weight and pulmonary exacerbations, to add a decade to the median life expectancy of CF patients. **CONCLUSIONS:** Modeling suggests that therapies that improve clinical risk factors for mortality in CF, including pulmonary function, weight and pulmonary exacerbations, may extend the lives of CF patients.

#### NEUROLOGICAL DISORDERS - Cost Studies

#### PND12

##### BUDGET IMPACT ANALYSIS OF ROUTINE TESTING FOR GENETICALLY BASED CARDIOPATHIES ASSOCIATED WITH HIGH RISK OF SUDDEN DEATH IN SPAIN: PRELIMINARY RESULTS

Fernández I<sup>1</sup>, García-Pavía P<sup>1</sup>, Ripoll T<sup>2</sup>, Boldeanu A<sup>3</sup>, Gracia A<sup>4</sup>, Ramírez de Arellano A<sup>4</sup>, Aceituno S<sup>5</sup>, Lizán L<sup>5</sup>, Puig-Gilbert J<sup>6</sup>, Salas E<sup>6</sup>

<sup>1</sup>Hospital Universitario Puerta del Hierro, Madrid, Spain, <sup>2</sup>Hospital Son Llàtzer, Palma de Mallorca, Spain, <sup>3</sup>FERRER-inCode, Barcelona, Spain, <sup>4</sup>Ferrer Grupo, Barcelona, Spain, <sup>5</sup>Outcomes 10, Castellón, Spain, <sup>6</sup>GENDIAG, Barcelona, Spain

**OBJECTIVES:** To estimate the economic impact of introducing the test for diagnosing the five cardiopathies associated to SCD related to the currently best known genes in Spain: 1. Hypertrophic Cardiomyopathy (HCM); 2. Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC); 3. Long-QT Syndrome (LQTS); 4. Brugada Syndrome (BrS); and 5. Catecholaminergic Polymorphic Ventricular Tachycardia (CPVT). **METHODS:** A 3-year budget impact analysis was carried out based on international sources of epidemiological and health care resource utilization data; local input costs and market share, and expert opinion. Two scenarios were compared: current clinical practice (with no genetic testing) vs. alternative practice (with genetic testing). The perspective adopted was that of the Spanish National Healthcare System (NHS). All costs referred to € 2012. **RESULTS:** The target population at risk of SCD was estimated on 25,220 patients for year 1; 26,352 for year 2, and 26,340 for year 3. Genetic testing would be conducted in 350, 550 and 700 patients in 2012, 2013 and 2014, respectively. The budget impact of introducing the genetic testing would imply an additional cost of € 309,187, € 532,311, and € 724,404, respectively. Genetic testing compared to current practice would imply cost savings of € 10,152 and of € 41,062, in the first year; of € 30,327 and of € 84,026, in the second, and of € 57,269 and of € 126,660 in the third year derived from two reasons: preventing new events in patients at risk and from averting follow-up in patients at no risk, respectively. **CONCLUSIONS:** Potential cost savings derived from preventing new events and unnecessary follow-up may overcome the costs of introducing the genetic testing for HCM, ARVC, LQTS, BrS and CPVT in the Spanish NHS.

#### PND13

##### BUDGET IMPACT ANALYSIS AND UPDATE OF A COST EFFECTIVENESS EVALUATION FOR ALPHA (α) POLYMORPH RIFAXIMIN FOR THE TREATMENT OF ACUTE HEPATIC ENCEPHALOPATHY

Cardona DP<sup>1</sup>, Zapata L<sup>2</sup>, Ceballos M<sup>1</sup>, Diez F<sup>3</sup>, Rico I<sup>2</sup>, Zavala A<sup>3</sup>

<sup>1</sup>Universidad De Antioquia- Facultad De Química Farmacéutica, MEDELLIN, ANTIOQUIA, Colombia, <sup>2</sup>Guía Mark, Mexico, DF, Mexico, <sup>3</sup>Guía Mark, México, DF, Mexico

**OBJECTIVES:** Cirrhosis and its complications, such as hepatic encephalopathy (HE) are the sixth cause of general mortality in Mexico. The objective is to update costs,