PNL10

### THE SOCIOECONOMIC IMPACT OF NARCOLEPSY Dodel R<sup>1</sup>, Peter H<sup>2</sup>, Walbert T<sup>3</sup>, Spottke EA<sup>1</sup>, Berger K<sup>4</sup>, Siebert U<sup>5</sup>,

Kesper K<sup>6</sup>, Becker H<sup>6</sup>, Mayer G<sup>7</sup>

<sup>1</sup>Friedrich-Wilhelms-University, Bonn, Germany; <sup>2</sup>Philipps University, Marburg, Germany; <sup>3</sup>University of Bonn, Bonn, Germany; <sup>4</sup>MERG Medical Economics Research Group, München, Germany; <sup>5</sup>Harvard Medical School, Boston, MA, USA; <sup>6</sup>Marburg University, Marburg, Germany; <sup>7</sup>Hephata Kliniken, Schwalmstadt-Treysa, Germany

**OBJECTIVES:** Narcolepsy is a chronic sleep disorder characterized by excessive daytime drowsiness, sleep attacks, cataplexy, hypnagogic hallucinations and sleep paralysis. The aim of the study was to assess the economic burden of patients suffering from narcolepsy. METHODS: In a cross-sectional study, we used a standardized telephone interview and a mailed questionnaire to calculate the economic and social burden of 75 narcoleptic patients (mean age:  $48.9 \pm 15.2$ ; f:m: 29:46), who met the International Sleep Disorder Classification criteria. Health-related quality of life was assessed by using the SF-36 and the EQ-5D. From a societal perspective, we calculated all direct and indirect costs using EUR2002. RESULTS: The total annual costs amounted to 16,798 ± 18,976€ per patient. Direct costs added up to  $3284 \pm 3600 \in$  and included hospital costs (1193  $\pm 2202 \in$ ), in-patient rehabilitation (535  $\pm$  1772€), ambulatory diagnostics  $(18 \pm 3 \in 0)$ , ambulatory care  $(88 \pm 55 \in)$  and drug costs (narcolepsy medication: 1120 ± 1530€). Approximately 50% of narcoleptic drug costs were due to the newer wake-promoting drug Modafinil. Modafinil is known to be a potent but also more expensive treatment. Total annual indirect costs were 13,515 ± 18,411€ per patient and are mainly caused by early retirement. Sleep attacks correlated significantly with early retirement and higher indirect costs in comparison to patients without them (p = 0.012). CONCLUSIONS: The socioeconomic impact of narcolepsy on society is considerably high. As in most other neurological diseases, the indirect costs outnumber the direct medical costs. Appropriate treatment is required to help patients to continue their working life and to minimize indirect costs.

# PNLII

#### EFFECT OF COMORBIDITIES ON MEDICAL CARE USE AND COST AMONG PATIENTS WITH PARTIAL SEIZURE DISORDER Lee WC<sup>1</sup>, Arcona S<sup>2</sup>, Thomas SK<sup>2</sup>, Wang Q<sup>1</sup>, Hoffmann MS<sup>1</sup>, Botteman MF<sup>1</sup>, Pashos CL<sup>3</sup>

<sup>1</sup>Abt Associates Inc, Bethesda, MD, USA; <sup>2</sup>Novartis Pharmaceuticals Corporation, East Hanover, NJ, USA; <sup>3</sup>Abt Associates Inc, Cambridge, MA, USA

**OBJECTIVE:** Comorbidities in patients with seizure disorders impose significant burdens on patients and families. The purpose of this study was to assess the effect of comorbidities on medical care use and cost among patients with partial seizure disorder who were also refractory to anti-epileptic drug (AED) monotherapy. METHODS: Retrospective data from PharMetrics claims database, which includes 57 managed care plans, were collected for adult patients treated with AEDs between January 1, 2000 and March 30, 2000. Patient data were analyzed over a 6-month baseline period prior to treatment failure (on carbamazepine, phenytoin, or valproic acid monotherapy), and over a 12-month follow-up period. The Charlson Comorbidity Index (CCI) was calculated for each patient. Econometric analysis of total cost and a logistic regression with hospitalization as the dependent variable, examined the impact of the CCI, controlling for age, gender, geographic location, observation period, and AED therapy during follow-up. RESULTS: Data from 549 patients were analyzed. Sixty-percent of patients were male; 25.3% of patients were 18-30 years old, 35.2% 31-45, and 39.5% were

# Abstracts

≥46. Headache (10.6%), migraine (4.7%), depression (6.9%) and brain tumor (4.0%) were frequently recorded, with headache (p < 0.05) and migraine (p < 0.01) more common among females. Hypertension and hyperlipidemia occurred most often in the oldest age category (p < 0.001), being reported among 20.3% and 10.1% of patients >46 years old. During follow-up, among patients with a CCI > 1, the odds of hospitalization were nearly 3.5 times greater than for patients without recorded comorbidities (OR = 3.46, p < 0.05), while treatment costs for all medical care were 1.3 times greater (p < 0.10). CON-CLUSIONS: These analyses suggest that, for patients refractory to initial standard AED monotherapy, the presence of comorbidities substantially increase medical care use and costs for managed care plans.

PNL12

### HEALTHCARE UTILIZATION AND SOCIOECONOMIC ASPECTS OF NEUROMUSCULAR DISEASES

 <sup>1</sup>Friedrich-Wilhelms-University, Bonn, Germany; <sup>2</sup>Philipps-University, Marburg, Germany; <sup>3</sup>Clinic Darmstadt, Darmstadt, Germany;
<sup>4</sup>University Erlangen, Erlangen, Germany; <sup>5</sup>University Muenster, Muenster, Germany; <sup>6</sup>Clinic of Diagnostics, Wiesbaden, Germany;
<sup>7</sup>Otto-von-Guericke University, Magdeburg, Germany

**OBJECTIVES:** To assess the healthcare utilization of common neuromuscular disease. METHODS: In total, 79 patients (mean age: 53.9  $\pm$  18.0; w/m: 45:34) with Amyotrophic Lateral Sclerosis (ALS, n = 26), Myasthenia Gravis (MSG, n = 35) or Facioscapulohumeral Muscular Dystrophy (FSHD, n = 18) were interviewed for changes of employment and number of health institution visits before the final diagnosis has been established. Additional health care utilization of the last 12 months were assessed. RESULTS: The final diagnosis has been established following an average of  $3.4 \pm 2.4$  (ALS),  $3.4 \pm 2.8$  (FSHD) and 2.5 $\pm$  1.6 (MSG) outpatient contacts with medical institution. The number of hospitalizations until final diagnosis was not different for the three diseases  $(1.3 \pm 1.0 \text{ (ALS)}, 1.1 \pm 2.7 \text{ (FSHD)})$  and  $0.6 \pm 06$  (MSG)). For the last 12 months the patients reported mean ambulant visits of  $12 \pm 9$  (ALS),  $6 \pm 5$  (FSHD) and  $15 \pm$ 10 (MSG). Hospitalization was reported by 85% of the ALS-, 16% of the FSHD-, and 74% of the MSG-patients. The mean number of hospitalization was  $1.23 \pm 0.76$  (ALS),  $0.33 \pm 0.77$ (FSHD) and  $1.31 \pm 0.99$  (MSG). Early retirement caused by the neuromuscular disease was reported by 6% of the MSG patients, 19% of the ALS and 33% of the FSHD patients. Still at work were 49% of the MSG, 56% of the FSHD and 12% of the ALS patients. These patients were absent from work due to the neuromuscular disease for a mean of  $14 \pm 24 d$  (ALS),  $13 \pm 17 d$ (MSG) and  $5 \pm 6 d$  (FSHD). CONCLUSIONS: The results of the study underline the socioeconomic impact of neuromuscular diseases in Germany. Especially the high number of outpatient visits during a 12-month period represent a relevant health care utilization. In particular the influence of the employment state of the patients contributes significantly to the socioeconomic impact on society.

PNL13

# PROFILE OF PATIENTS SUFFERING FROM RESTLESS LEGS SYNDROME AND ESTIMATION OF THEIR ANNUAL COST IN AN AMBULATORY CARE SETTING, IN FRANCE

<u>Maurel F</u><sup>1</sup>, Girard B<sup>1</sup>, Crochard A<sup>2</sup>, Henri M<sup>2</sup>, El Hasnaoui A<sup>2</sup>, Le Pen C<sup>3</sup>

<sup>1</sup>Aremis Consultants, Paris, France; <sup>2</sup>GlaxosmithKline, France; <sup>3</sup>Aremis Consultants and Paris Dauphine University, Paris, France

### Abstracts

**OBJECTIVES:** To characterize patients suffering from restless legs syndrome (RLS) and assess their annual health care resources consumption in comparison with a population of average ambulatory patients seen by General Practitioners (GPs), in France. METHODS: This study was based on anonymous individual longitudinal medical records of adult patients suffering from RLS provided by physicians from a permanent panel of representative French GPs. RLS was defined accordingly to established diagnostic criteria. Patients with at least one complaint of legs and/or sleep symptoms suggestive of RLS in 2003 were included. Data about patients' socio-demographic characteristics, clinical status, medical resources consumption and sick leaves over one year were collected retrospectively. For the cost comparison, RLS patients were matched for sex and age to a corresponding random population of patients followed by the same GPs. Average annual costs in € were estimated from the perspective of Health Insurance. RESULTS: A total of 515 RLS patients were included. Mean age was 63.8 years and 76% were female. 14% of patients had both complaints of leg and sleep symptoms, 59% only leg troubles and 27% only sleep disturbances. All together, RLS patients consumed significantly (p < 0.0001) more health care resources than those from the comparison group. On average in 2003, they saw 11.6 times their GPs (versus 4.6 in the comparison group), 7 investigations were prescribed (versus 4.3) and they had had 46.8 drug prescriptions (versus 16.5). The mean annual medical cost of RLS patients' follow-up by GPs was twice higher than that of average consulting patients (840€ versus 391€, p < 0.0001). CONCLU-SIONS: This study shows that patients satisfying to validated diagnostic criteria consumed significantly more medical resources than "ordinary" patients in primary care bearing in mind that RLS remains an unknown and under-diagnosed condition. This population deserves thus a special attention in order to optimize the treatment.

### PNL14 THE COST-EFFECTIVENESS OF TREATING PATIENTS WITH RESTLESS LEGS SYNDROME (RLS) USING ROPINIROLE <u>Moore AP<sup>1</sup></u>, Lloyd A<sup>2</sup>, Scott DA<sup>2</sup>, Connolly M<sup>3</sup>, Dixon S<sup>4</sup>

<sup>1</sup>The Walton Centre for Neurology and Neurosurgery, Liverpool, UK; <sup>2</sup>Fourth Hurdle; <sup>3</sup>GlaxoSmithKline, London, Middlesex, UK; <sup>4</sup>Sheffield University, Sheffield, South Yorkshire, UK

**OBJECTIVES:** Idiopathic RLS (Ekbom syndrome) is a sensorimotor disorder that leads to disrupted sleep and poor quality of life. Until now, there have been no internationally approved treatments for this disorder. This study evaluated costs and outcomes resulting from the use of ropinirole in patients with RLS. METHODS: Data were combined from 553 patients enrolled in two matching, pivotal, randomized, 12-week, double-blind, placebo-controlled studies. Patients with moderate-to-severe RLS received ropinirole or placebo, with a maximum allowable dose of 4 mg/day. The primary outcome measure was the International Restless Legs Scale (IRLS). IRLS scores at baseline and study endpoint were mapped to the multi-attribute utility instrument EQ-5D based on expert opinion to derive Quality-Adjusted Life Years (QALYs). Costs of study drug, concomitant neurological medications and cost of adverse events were applied in the model from the perspective of the UK NHS. Lower cost per QALY gained indicates better cost-effectiveness. RESULTS: Based on combined analysis of the entire treatment population over 12 weeks, the QALYs gained for ropinirole and placebo were 0.095 (0.082-0.106) and 0.075 (0.063-0.086), respectively. The mean costs per patient for ropinirole and placebo were £210.52 (£197-£223) and £42.34 (£34-£53), respectively. The incremental QALYs and costs were 0.020 (0.002-0.037) and £168.18 (£150–£187), respectively, resulting in an incremental cost per QALY of £8405 (£4557–£41,524). Extrapolation of IRLS scores at trial endpoint to 52 weeks improved the incremental QALY to £6748. For patients reporting more severe sleep disturbance or more severe symptoms at baseline, the cost-effectiveness ratios improved to £5810 (£3210–£20,177) and £4587 (£2881–£10,508), respectively. CONCLUSIONS: In the absence of an active-treatment comparator, this analysis found that treatment of moderate-to-severe RLS with ropinirole is cost-effective compared with placebo using conventional UK cost-effectiveness standards, particularly in patients with more severe sleep disturbance and severe RLS symptoms at baseline.

PNL15

## RETROSPECTIVE EVALUATION OF THE DOSE OF DYSPORTÒ AND BOTOXÒ IN THE CLINICAL MANAGEMENT OF CERVICAL DYSTONIA OR BLEPHAROSPASM—THE REAL DOSE STUDY EXPANSION—COST CONSIDERATIONS BASED ON DRUG START

<u>Magar R<sup>1</sup></u>, Ahmed F<sup>2</sup>, Findley L<sup>3</sup>, Larsen JP<sup>4</sup>, Pirtosek Z<sup>5</sup>, Slawek J<sup>6</sup>, Rùžièka E<sup>7</sup>

<sup>1</sup>Thomson Corporation, Secaucus, NJ, USA; <sup>2</sup>Hull Royal Infirmary, UK; <sup>3</sup>Essex Neuroscience Unit, UK; <sup>4</sup>Central Hospital of Rogaland, Norway; <sup>5</sup>University Clinical Centre, Slovenia; <sup>6</sup>St. Adalbert Hospital, Poland; <sup>7</sup>Charles University, Czech Republic

**OBJECTIVE:** Assess utilization of Dysport and BOTOX for cervical dystonia and blepharospasm and compute the cost consequences of toxin selection. METHODS: Six European study sites abstracted drug utilization data from the records of their patients who had received Dysport then BOTOX or BOTOX then Dysport in a drug crossover that occurred in clinical practice. To reduce potential selection bias and confounding variables, patient records were screened for study inclusion/exclusion criteria during scheduled clinic visits. Patients were screen-qualified if they were 18 years of age, medically stable, responsive to persistent toxin therapy for 1 year before and after drug crossover, did not receive other medications that affect neuromuscular transmission, and were not involved in another drug study. **RESULTS:** A total of 132 screen-qualified patients were assessed. Ratios of mean dose (units) Dysport: BOTOX ranged from 2:1 to 11:1, with 88% of patients greater than or equal to 3:1, regardless of study site or direction of drug crossover. When current UK pricing for BOTOX and Dysport is applied to distribution of ratios, patients started on Dysport and switched to BOTOX (N = 94) result in an incremental net savings of £1572.4 or an average savings of £16.7 per patient. When patients were started on BOTOX and switched to Dysport (N = 38), an incremental net cost of £252.9 or an average cost of £6.7 per patient is realized. CONCLUSION: BOTOX utilization likely leads to net cost savings compared with Dysport based on utilization and current pricing for the UK.

PNL16

### A COMPARATIVE STUDY ON RESOURCE USE, COSTS AND CAREGIVER BURDEN BETWEEN RASAGILINE AND ENTACAPONE IN FLUCTUATING PARKINSON'S DISEASE (PD) PATIENTS

Roch B<sup>1</sup>, Despiegel N<sup>2</sup>, François C<sup>1</sup>, Goren T<sup>3</sup>

<sup>1</sup>H. Lundbeck A/S, Paris, France; <sup>2</sup>H.Lundbeck A/S, Paris, France; <sup>3</sup>Teva Pharmaceuticals, Petach Tikva, Israel

**OBJECTIVES:** To compare the costs of PD when using rasagiline and entacapone to treat patients that experienced motor fluctuations. **METHODS:** An 18-week randomised double-blind controlled clinical trial (RCT) LARGO, evaluating the safety and efficacy of rasagiline 1 mg/d, entacapone 200 mg with levodopa