OBJECTIVES: Multiple sclerosis (MS) is a chronic progressive neurologic disease and one of the major causes of disability among young adults. Through the clinical manifestations and symptoms of MS are diverse, disease severity is generally measured by ambulation based Expanded Disability Severity Scale (EDSS). While EDSS captures well the level of disability due to the involvement of lower motor neurons, including bladder, its ability to capture other aspects such as fatigue and mental function are poor. The aim of this study was to explore the relationship between two patient-based measures, a self-administered EDSS and Multiple Sclerosis Impact Scale (MSIS-29), with a psychometrically validated instrument measuring the physical (20 items) and psychological (nine items) impact of MS.

METHODS: In total, 553 Finnish persons with MS (PwMS) drawn from the membership register of the national patient association completed a postal survey, including EDSS and MSIS-29. RESULTS: PwMS at every (0–9) impairment level of the EDSS scale were represented. The mean EDSS score was 4.0, indicating moderate disability. The physical impact of MS was strongly related to disease severity, whereas the psychological burden of MS increases steadily with self-assessed disease severity, whereas the psychological burden does not go hand in hand with the self-assessed severity of disease.

CONCLUSIONS: The subjective physical burden of MS increases steadily with self-assessed disease severity, whereas the psychological burden does not go hand in hand with the self-assessed severity of disease.

PND76
CHALLENGES IN TRANSLATING THE MULTIPLE SCLEROSIS INTERNATIONAL QUALITY OF LIFE (MUSIQOL) QUESTIONNAIRE IN 57 LANGUAGES

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OBJECTIVES: The Multiple Sclerosis International Quality of Life (Musiqol) questionnaire is a self-administered, measure designed to evaluate the quality of life of patients with multiple sclerosis (MS) The Musiqol was co-developed with persons living with MS. It is composed of 31 items describing nine dimensions (activity of daily living, psychological well-being, symptoms, relationships with friends, relationships with family, relationships with health care system, sentimental and sexual life, coping, and mobility). The aim of this study is to present the challenges faced during the translation of the Musiqol in 57 additional languages representing seven language families.

METHODS: In each country, the translation process (linguistic validation) was conducted by a linguistic expert, using either the standard forward-backward methodology or the adjusted process, including cognitive interviews with six patients. The basis for discussion was the concept list developed in collaboration with the authors.

RESULTS: Semantic and cultural issues emerged during the process. In some cases, changes in item content and cultural context or the translation process were introduced to preserve content validity with your cultural context. The challenges faced during the translation in 57 additional languages. The collaboration with the developers and the patients interviews helped to solve the major issues.

PND77
RELAPSING REMITTING MULTIPLE SCLEROSIS PATIENTS INITIATED ON ORAL DMF REPORT A BETTER QUALITY OF LIFE COMPARED TO PATIENTS ON PLATFOR FM THERAPIES AS MEASURED BY EQ-5D

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OBJECTIVES: Multiple sclerosis (MS) is a chronic inflammatory disease that can have physical, psychological, and social impacts, reducing health-related quality of life (HRQoL). OBJECTIVES: To compare the HRQoL in patients initiated on delayed-release interferon β-1a or glatiramer acetate (ABCRe) therapies. METHODS: Data were identified from the Adelphi MS Disease Specific Programme, a cross-sectional study of MS patients in five EU countries and the US. Relapsing Remitting MS (RRMS) patients, receiving DMF or ABCRe therapies with treatment duration greater than 12 months. HRQoL was assessed using the Hambourg Quality of Life Questionnaire in MS (HAQUAMS), consisting of five domains (fatigue/thinking, mobility/upper limb, mobility/lower limb, social function, sex life) in which higher scores indicate poorer HRQoL. Inverse-probability-weighted regression-adjustment estimated average treatment effects (ATEs) on the HAQUAMS across DMF and ABCRe cohorts, utilizing a propensity score generated from age, gender, EDSS score at current treatment initiation, BMI, duration of current treatment, line of therapy, time since MS diagnosis, and number of comorbid conditions. RESULTS: A total of 252 (29 DMF, 223 ABCRe) patients completed the HAQUAMS questionnaire. The overall HAQUAMS score was significantly lower in DMF patients compared to ABCRe patients (ATE = -0.45, p < 0.01, vs. 1.95). Significant differences were observed in four of the five subscales, as fatigue/thinking (ATE = -0.47, p < 0.01, vs. 1.95), lower limb mobility (ATE = 0.34, p = 0.09, 1.84), social function (ATE = -0.001, p = 2.95, vs. 2.4), and sex life (ATE = -0.45, p < 0.01). The ATE for upper limb mobility score was not statistically significant (ATE = 0.15, p = 0.075, vs. 1.38). CONCLUSIONS: RRMS patients on DMF had significantly better HRQoL as measured by the HAQUAMS, versus RRMS patients on ABCRe therapies.

PND79
A SYSTEMATIC REVIEW OF THE HUMANISTIC BURDEN OF DISEASE IN PATIENTS WITH FABRY DISEASE

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OBJECTIVES: Fabry disease is a rare, progressive, X-linked lysosomal storage disorder caused by deficiency of α-galactosidase A. Multiple major organs are affected, impacting on health-related quality of life (HRQoL). Symptomatic disease requires lifelong treatment with intravenous enzyme replacement therapy (ERT); two products available, which has been shown to improve long-term outcomes, delay organ damage and improve HRQoL. We present the results of a systematic review of the cumulative burden of Fabry disease. METHODS: We searched MEDLINE, Embase and congress proceedings to identify studies reporting general HRQoL in patients with Fabry disease. RESULTS: The search identiﬁed 30 relevant publications reporting data for ERT-treated and -untreated male and female adult and paediatric patients. The majority of studies assessed HRQoL using the 36-item Short-Form Health Survey (SF-36; n = 18) and/or 5-dimension European Quality of Life instrument (EQ-5D; n = 8). HRQoL was reduced compared with the general population (n = 8), ERT-treated patients (n = 4) had a better health-related quality of life than the general population (n = 4); furthermore, HRQoL deteriorated with age (n = 2) and with progressive disease (n = 2). Two clinical trials were identiﬁed (one placebo-controlled and one abzyme-controlled) that described HRQoL measured by the EQ-5D (n = 2). There were ﬁve analyses of registry data for patients receiving ERT; four studies demonstrated sustained HRQoL improvements with up to 5 years of agalsidase alfa treatment, and one study reported improvements after 1 and 2 years of agalsidase alfa therapy in two small Fabry disease cohorts. CONCLUSIONS: The limited available data suggest that this improved while on ERT. Further studies are required to quantify treatment-associated HRQoL outcomes.

PND80
HEALTH-RELATED QUALITY OF LIFE IN DOUBLE-BLIND PHASE III STUDIES OF BRIVARACETAM AS ADJUNCTIVE THERAPY OF PARTIAL-ONSET SEIZURES

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OBJECTIVES: To assess the effect of brivaracetam (BRV), a new adjunctive therapy of partial-onset seizures (POS), on health-related quality of life (HRQoL).

METHODS: Data from three previously reported Phase III trials of BRV in adults with refractory POS (NCT00490035, NCT00464269, NCT01261325) were pooled. The POLE-31-P was collected at randomization and after the 12-week treatment period or early termination. The QOLIE-31-P is an epilepsy-specific instrument with seven subscales and a Total score ranging from 0 (worse) to 100 (better HRQoL). Mean change in HRQoL was compared between patients receiving BRV 200 mg/day and placebo using ANCOVA with treatment, center, disease severity, and age as covariates. RESULTS: There were 422, 179, 524, and 235 patients in the placebo, BRV 50mg/day, 100mg/day, and 200mg/day groups, respectively. All treatment groups showed an improvement in Total score (F = 0.001, p = 0.001) from baseline to last observation in patients receiving BRV 50mg/day and placebo. QOLIE-31-P scores were similar at all time points other than the 12-week visit (p = 0.001; F = 12.7). 30.3% (213) of 701 patients were classified as responders to brivaracetam, 231 (82.3%) of 281 patients on BRV 200 mg/day reported a clinically meaningful improvement in the Total score, compared to the placebo group. CONCLUSIONS: Changes in HRQoL were small and generally comparable.
between treatment groups. Differences reflected the known efficacy and safety profile of BIV. Where reported for other AEDs, changes from baseline and treatment group differences are similarly small, raising questions about the appropriateness of short-term fixed-dose trials as a source of HRQoL data for adjunctive AEDs in refractory patients. Long-term assessments may be more informative. Supported by UCB.

NEUROLOGICAL DISORDERS – Health Care Use & Policy Studies

PND81 DOES CRGS PROVIDE PROPER GUIDES FOR AN EFFICIENT PHARMACEUTICAL PRESCRIPTION IN ALZHEIMER PATIENTS?

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Purpose: The main goal of this paper is to analyze pharmaceutical expenditure in Alzheimer patients from a European southeastern region (Valencian Region (Spain)), by using the clustering patients system Clinical Risk Group (CRGs). We focused on obtaining more information about Alzheimer patients, stabilizing a more accurate prediction of their resource consumption and individuating patterns of pharmacoeconomic use. METHODS: A cross-sectional study of the inhabitants of Valencian region with a population of 5,000,000 was carried out, using data extracted from Electronic Health Records for 2013. A sample of 24641 Alzheimer individuals were identified. RESULTS: From our sample 29.4% men and 70.6% women were found. The annual average cost per Alzheimer patient is € 1709.051. By gender, women's average cost is 1718.66 € while men average consumption is 1685.97 €. Age is the variable that most affect pharmaceutical cost, while severity levels are not capable to explain cost variability. CONCLUSIONS: Valuable information about pharmaceutical cost of Alzheimer patients was found. In contradiction to other studies, we found that the severity level does not provide a clear explanation of pharmaceutical cost variability.

PND82 DEVELOPMENT OF A SCREENING TOOL TO SUPPORT IDENTIFICATION OF PATIENTS WITH SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS)

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OBJECTIVES: Transition from RRMS to SPMS is difficult to diagnose. Here, we describe methodology for developing a screening tool that can help physicians to diagnose SPMS early. METHODS: Tool will be developed along 3 steps: Quantitative research: A retrospective cross-sectional study to describe differentiating characteristics between SPMS and late RRMS patients using Adelphi Real World database. 2791 MS patient records extracted from EDSS questionnaires were used. Disease activity variables will include disease characteristics, demographics, MS history, treatment history, daily activities, symptoms and clinical characteristics including MRI activity. Patients will be stratified based on EDSS and disease duration into: Early RRMS (control group), Late RRMS and Early SPMS: A multivariate regression analysis will identify the significant predictors of patient classification as ‘Late RRMS’ or ‘Early SPMS’ by physician. Qualitative research: (1) Open-ended qualitative interviews of patients (16 each in the US and Germany) – 8 RRMS and 8 SPMS patients with EDSS (5/10) to identify and characterize key variables will influence disease progression and treatment. (2) Semi-structured interviews will be performed on the data. RESULTS: A total of 15,515 MD patients with 12 months continuous enrollment, and 4,547 individuals with MD and 36 months continuous enrollment were identified, which 14.2% filled a previous prescription for an ACE-inhibitor. There were 340 patients with 12 months enrollment who had evidence of severe renal dysfunction, and 127 (37%) of those filled a subsequent prescription for a ACE-inhibitor. There were 94 (28%) patients with 36 months enrollment who had evidence of severe renal dysfunction, and 50 (53%) filled at least one subsequent prescription for an ACE-inhibitor. CONCLUSIONS: Cardio-protection treatment with ACE-inhibitors among MD patients is significant. Although severe renal dysfunction is not highly prevalent in this patient population, the treatment could be reduced despite a possible contraindication, especially in patients with severe disease. New therapies in development which address underlying disease rather than complications may enable patients to avoid potential contraindications.

PND83 COSTS ASSOCIATED WITH PATIENTS DIAGNOSED WITH RELAPSING-REMITTING MULTIPLE SCLEROSIS TAKING ONCE DAILY FINGOLIMOD CAPSULES IN THE UNITED STATES

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OBJECTIVES: Fingolimod oral tablets were approved in the United States (US) in September 2010 for the treatment of relapsing remitting multiple sclerosis (RRMS). The objective of this study is to assess the costs associated with Fingolimod treatment in patients diagnosed with RRMS in the US. METHODS: An administrative retrospective claims database was used to identify patients diagnosed with RRMS and were prescribed Fingolimod between January 2010 to December 2012 were included in the study. All patients ≥ 18 years of age and continuously enrolled in the same health plan for a year. Descriptive statistics and chi-square tests were performed on the data. RESULTS: There were a total of 28,477 patients that met the inclusion criteria for the study. The allowed dose for Fingolimod during the study period. However, the allowed amount by the health plan was $4624.21 ± 2070.58 and the actual paid amount was $4529.98 ± 2074.58. On average, patient’s deductible was $13.64 and $8.85 for patients prescribed Fingolimod during the study period. CONCLUSIONS: The cost of Fingolimod treatment for RRMS patients is higher and costing the health plan around $3552 for 3 months. The cost of the drug treatment was higher in southern of the US and males were paying more in general.

PND86 OVER-PREScripTION OF FINGOLIMOD IN GERMANY

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OBJECTIVES: Fingolimod is an orally available immune-modulatory drug for treating relapsing remitting Multiple Sclerosis (RRMS). It was approved by the European Medicines Agency (EMA) in 2013. One urgent safety concern (progressive multifocal leukoencephalopathy (PML) and cardiovascular events) has been reported in the meantime. Early benefit assessment by the Federal Joint Committee (G-BA) in 2012 and 2013 showed only additional benefit for a certain group of patients. Therefore the use of Fingolimod has widely been discussed in Germany. We analyzed prescriptions of Fingolimod and the impact of Health Technology Assessment (HTA) and drug safety warning. METHODS: We used routine data of the German Federal Joint Committee (G-BA) with more than 8.2 million insured, from 2012 to 2014. We looked for prescriptions of disease-modifying therapies (DMT) for patients with Multiple Sclerosis (MS). Diagnosis of MS was identified by G35 according to ICD-10. Considered DMT were Fingolimod, Gilantinec Ataletumab, Natalizumab, Interferon beta-1a, Interferon-