EUR. RESULTS: The overall prescribing of antiepileptics (N03) within outpatient setting of Montenegro during investigated period was 2.85 DTIDs, that was 232516.68 EUR. Although combination of sodium-valproate and valproic acid was prescribed approximately 13% (0.36 DTIDs), it participated in total expenses extensively more (40.28%, 93661.92 EUR). Newer antiepileptic agent, lamotrigin, was prescribed less than 4% (0.11 DTIDs), but it formed a one third of total costs (€33.28%, €77,377.08). The expenses for the two most frequently prescribed drugs phenobarbital and carbamazepine were almost equal (€25,439.04 and €21,199.20, 20.06%), although those drugs formed more than 80% of total prescribing. The participation of other drugs (sodium-valproate, clonazepam, gabapentin) in total expenses was about €14,839.44(6.38%). CONCLUSIONS: Our doctors mostly prescribed older, accessible, long-term experienced and lower priced antiepileptics. In order to fully estimate the expenses for the pharmacological management of epilepsy is rational or not, we have to explore this problem with more detail.

PND18

RUFINAMIDE IN THE ADJUNCTIVE TREATMENT OF LENNOX-GASTAUT SYNDROME (LGS): A COST EFFECTIVENESS ANALYSIS

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OBJECTIVES: To estimate relapse-associated cost savings due to reduction in MS-related hospitalization rates among natalizumab patients with relapsing multiple sclerosis (MS), including those with highly-active disease. METHODS: A probabilistic model was developed to estimate natalizumab-associated cost savings based on reductions in annualized MS-related hospitalization rates due to relapse. Hospitalization rate data were obtained from the randomized, double-blind, placebo-controlled, phase 3, natalizumab monotherapy clinical trial (AFFIRM). Among the 942 patients with relapsing MS who received natalizumab 300 mg (n = 627) or placebo (n = 315) intravenously for up to 116 weeks, those who reported ≥2 relapses in the prior year and ≥1 Gd+ enhancing lesions were considered highly-active (n = 148 for natalizumab, n = 61 for placebo). Natalizumab reduced the annualized MS-related hospitalization rate by 65% (p < 0.001) among all patients (0.034 natalizumab vs 0.097 placebo) and by 89% (p < 0.001) among those with highly-active disease (0.015 natalizumab vs 0.137 placebo). Cost savings associated with such reductions were assessed using MS hospitalization costs obtained from a random sample of the PharMetrics database ($19,750/episode, 2007 US Dollars). The model ran 1,000 simulations to estimate the mean costs of MS hospitalizations and associated 95% confidence intervals (CI). RESULTS: Due to relapse-associated hospitalization rate reductions, the 2-year per-patient MS hospitalization cost was $1,338 (95% CI: $842, $1964) for natalizumab and $3828 (95% CI: $2628, $5281) for placebo, resulting in a cost savings of $2490 (95% CI: $1,143, $3980). In patients with highly-active disease, the 2-year per-patient MS hospitalization cost was $604 (95% CI: $86, $1643) for natalizumab and $5436 (95% CI: $2,558, $9593) for placebo, resulting in a cost savings of $4832 (95% CI: $1988, $9111). CONCLUSIONS: Natalizumab significantly reduced relapse-associated costs of MS-related hospitalizations in patients with relapsing MS, with the magnitude of reduction being even larger among those with highly-active disease.

PND20

MEASURING THE IMPACT OF NARCOLEPSY ON QUALITY OF LIFE: A SYSTEMATIC REVIEW

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OBJECTIVES: Narcolepsy is a disease resulting in excessive daytime sleepiness (EDS) and cataplexy (an abrupt temporary loss of voluntary muscular tone, sometimes evoked by an emotional stimulus). Narcolepsy affects more than 20,000 people in the UK and has many implications for health-related quality of life (HRQL). The objective of our systematic review was to identify and assess the suitability of instruments used to measure the impact of narcolepsy on HRQL. METHODS: A systematic search of Scopus (1966–2008) was conducted using terms synonymous with “narcolepsy” combined with terms associated with measuring “QoL”. Once the measures were identified, further searches were undertaken to explore their use, development history and demonstrated measurement properties.
RESULTS: A total of 141 abstracts were screened yielding 18 studies that used patient-reported outcome (PRO) measures. In total, 13 PROs were used to evaluate symptoms, sleep disorders, anxiety/depression, and HRQL, most of which can be more accurately described as health status (SF-36, EQ-5D) or satisfaction (QLI) measures. Only two PROs were narcolepsy-specific: the Ullanlinna Narcolepsy Scale (UNS) and Stanford Narcolepsy Questionnaire, both measuring symptoms. No narcolepsy-specific HRQL questionnaires have been used to date. Generic measures such as the SF-36, QLI and the EQ-5D can be useful when making comparisons with other medical conditions but have limited value for assessing the full impact of narcolepsy because they include irrelevant items and exclude relevant issues. Furthermore, the generic measures do not demonstrate measurement properties relevant to this specific population nor do they demonstrate adequate development histories as required by regulatory bodies. CONCLUSIONS: There is an absence of instruments measuring narcolepsy-specific HRQL. Existing generic measures are likely to underestimate the full impact of narcolepsy on HRQL and therefore underestimate the full potential benefits of new treatments. A new questionnaire, which adheres to current regulatory guidelines, is therefore needed to assess the full impact of narcolepsy on HRQL.

SYMPTOM SEVERITY IN PARKINSON’S DISEASE SCALE (SSPDS): A NEW PATIENT-REPORTED OUTCOME MEASURE OF PARKINSON’S DISEASE SEVERITY
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OBJECTIVES: To evaluate the psychometric properties of the Symptom Severity in Parkinson’s Disease Scale (SSPDS), a new developed Parkinson’s disease (PD) specific patient-reported outcome (PRO) measure reflecting the patients’ perspective on their motor and non-motor symptoms. METHODS: Data were analyzed from a cross-sectional, community-based sample of 235 patients with idiopathic PD, who completed a set of standardized questions including the SSPDS, the short-form Parkinson’s Disease Questionnaire (PDQ-8) and the EQ-5D. RESULTS: Confirmatory factor analysis confirmed six factors: four factors of health status (“bodily discomfort”, “mobility”, “cognitive functioning” and “emotional well-being”), one factor for the total health status, and one of non-motor symptoms worsened by ADRs (ADR_NMS score). The 23-item SSPDS showed excellent internal consistency (Cronbach’s alpha between 0.70 and 0.89 for all health status scores, mean alpha was 0.79). Reproducibility for the total score (ICC = 0.82) was high. ICC for single scores ranged from 0.42 for bodily discomfort to 0.88 for mobility. Concurrent validity for the total and individual SSPDS scores was good as reflected by high Pearson’s r correlations with the PDQ-8 (r = 0.59 for cognitive functioning to r = 0.77 for the total score) and moderate to high correlations with the EQ-5D (r = −0.40 to r = −0.64). The ADR_NMS score was clearly separated from the other SSPDS scores, as shown by low correlations with the SSPDS health status scores (r = 0.19 for emotional well-being to r = 0.33 for mobility) and other measures (r = −0.14 for the EQ-5D VAS to r = −0.24 for the PDQ-8). CONCLUSIONS: The SSPDS is a valid and reliable PD-specific PRO measure to evaluate the severity of motor and non-motor symptoms. These symptoms load on the health status dimensions “bodily discomfort”, “mobility”, “cognitive functioning” and “emotional well-being”. Additionally, it identifies symptoms that are caused or affected by adverse drug reactions (ADRs). It is short and easy to complete in daily routine.

ELICITING UTILITY SCORES FOR HEALTH STATES ASSOCIATED WITH LENNOX-GASTAUT SYNDROME
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OBJECTIVES: To capture utility values for health states related to Lennox-Gastaut Syndrome (LGS), a severe form of childhood epileptic encephalopathy. METHODS: Four health state (HS) descriptions of LGS outcomes and 5 HS descriptions of common adverse events of anti-epileptic treatments for LGS were developed following literature review and extensive consultation with clinical experts. HSs were defined by tonic-atonic (drop attack) seizure frequency (SF). For LGS outcomes, the anchor state (HS-1) was described by frequency of 21–28 seizures per week; HS-2 a reduction of ≤50% in SF; HS-3 a reduction of ≤50% and ≤75% in SF and HS-4 a ≥75% reduction in SF. All HSs were piloted with 9 members of the UK general public. Time trade off interviews (TTO) were conducted with 119 members of the general public of whom 48% were caregivers/parents of children aged 4 to 18. A secondary analysis involved the participants rating each LGS health state on a visual analogue scale (VAS) and using the EQ5D. RESULTS: The mean utility scores for HS-1, HS-2, HS-3 and HS-4 were 0.393, 0.461, 0.605 and 0.699 respectively using TTO; 0.02, 0.414, 0.556 and 0.677 respectively using VAS; 0.02, 0.100, 0.500 and 0.596 respectively using EQ-5D. Differences between all LGS HSs and the anchor HS were significant (p < 0.0001) except for HS-2 using EQ5D. The preferences were reasonably consistent across age groups and gender. Caregivers/parents gave slightly higher scores for the health states only via TTO method. For adverse events the dis-utility score was 0.108 for concentration problems, 0.135 for weight loss, 0.174 for somnolence, 0.190 for rash and 0.193 for Nausea/Vomiting. CONCLUSIONS: The results demonstrate that drop attack SF correlates with poorer quality of life and show in a UK community sample a preference for treatment outcomes associated with a greater than 50% reduction in drop attack SF.

RELATIONSHIP BETWEEN CHANGES IN EQ-5D DERIVED UTILITY SCORES AND CHANGES IN IRLS SUM SCORES FROM A MAPPING EXERCISE IN TWO PHASE III CLINICAL TRIALS
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Introduction: Generic health-related quality of life data such as those obtained from the EQ-5D are not always available in a clinical programme. However, these data are required in reimbursement submissions. In the absence of direct measurement, such data may be estimated by mapping from a disease specific instrument. OBJECTIVES: 1) To map the elements in disease specific IRLS (International Restless Leg Scale) questionnaire against the elements in EQ-5D, and 2) To determine the relationship between changes in the EQ-5D derived utility scores and changes in the IRLS sum scores. METHODS: Each level of each question in the IRLS questionnaire, was mapped against a level of the EQ-5D based on clinical experts’ opinion. The utility scores were subsequently derived for two phase III clinical studies using the established algorithm. Simple OLS regression analyses were performed for the changes in utility scores on the changes in the IRLS sum scores from baseline to end of the maintenance period in order to estimate the average impact of a unit change on the IRLS for utility. RESULTS: Mobility and self-care dimen-