Abstracts

10, with 10 being death). For most patients, MS will progress from an episodic disorder (relapsing-remitting MS) to a more progressive state (secondary progressive MS). We conducted a systematic review of the literature to determine how health related quality of life, as measured by health utilities, changes with the increasing neurological disability associated with different stages of MS. METHODS: Employing pre-defined search terms and inclusion/exclusion criteria, systematic searches were conducted in MEDLINE, EMBASE, PsycINFO, Health Economic Evaluation Database (HEED), NHS Economic Evaluations Database (NHS/EED), and the UK National Institute for Health and Clinical Excellence (NICE) website. All databases were searched from 1 January 1993 to 5 August 2008. Data extraction was validated by an independent reviewer. RESULTS: We identified 16 studies reporting health utilities associated with health states of MS. EQ-5D was the most common preference elicitation instrument. Health utilities ranged from 0.80 to 0.89 for patients with an EDSS score of 1, from 0.49 to 0.71 for patients with an EDSS score of 3, from 0.39 to 0.54 for patients with an EDSS score of 6.5, and from -0.19 to 0.08 for patients with an EDSS score of 9 with some patients valuing their health states as worse than death. CONCLUSIONS: MS has a significant impact on quality of life. Utilities decrease significantly with increasing neurological disability. Without taking into consideration EDSS score, there appears to be no difference in health utilities between RRMS and SPMS patients and the variation in health utilities appears to be mainly explained by the severity of the disability. Utilities also decreased significantly during relapse phases.

THE USE OF ELECTRONIC PATIENT-REPORTED OUTCOMES WITHIN CENTRAL NERVOUS SYSTEM PROTOCOLS

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Perceptive Informatics, Waltham, MA, USA, ²Perceptive Informatics, Nottingham, UK OBJECTIVES: Central Nervous System (CNS) studies often incorporate the use of patient-reported outcomes (PROs) because of the nature of disorders being studied and their dependence on the subjective reports of study subjects1. To date, limited data has been published that sheds light on the types of instruments that are collected electronically (ePRO) in CNS trials. This research studied the breadth and depth of ePRO use through the analysis of a data set containing details of ePRO use in phase I-IV CNS drug trials. METHODS: A study of the characteristics of ePRO use in CNS clinical drug trials was undertaken to understand the breath of CNS disorders areas in which ePRO is being used as well as to understand how ePRO is being used within these trials. A dataset of 91 clinical trials was analyzed by using fields that describe each protocol's key elements including ePRO instrument, Phase, Assessment Frequency, Disorder and Target Population. RESULTS: The analysis determined that Depression and sleep disorders respectively represented 33.3% and 34% of ePRO use for this dataset. Overall, ePRO was used in 12 different CNS disorders. ePRO was most often used to collect primary efficacy data (24%), but other uses included secondary efficacy (22%) and safety (4.4%) data. The most common reporting frequency was for screening or study eligibility assessment (24%); this was followed closely by daily (19.8%) assessment. Of interest was that 79% of the time, a named instrument is used as opposed to a diary or symptom questionnaire (21%). CONCLUSIONS: This research shows that PROs are not only being collected electronically, but that ePRO use within CNS clinical trials is both broad and deep. Limitations of this study include the clinical trials of this dataset which can not be necessarily generalized as representative of all CNS ePRO use.

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CANADIAN PATIENT SURVEY TO ASSESS PATIENTS' PLIGHT TO MOVEMENT DISORDER DIAGNOSES AND BOTULINUM TOXIN TYPE-A (BONTA) TREATMENT – FINAL RESULTS

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Canada, ³', ', Canada

OBJECTIVES: To assess and describe the diagnostic and treatment pathways of movement disorders responsive to BoNTA, Allergan Units and assess the types and number of health care professionals seen by patients before their movement disorder diagnosis was made and the length of time from onset of symptoms to diagnosis. METHODS: Patients with movement disorders completed a 19-question survey developed by the Canadian Movement Disorders Survey Group. Questions included patient demographics, length of time from onset of symptoms, number and types of physicians seen, other diagnoses made, number of patients treated with BoNTA and distance traveled. RESULTS: In this final analysis, 879 patients with movement disorders responsive to BoNTA were surveyed. Majority of the patients were female (72%), traveling an average of 69 km one-way. Most common movement disorder diagnoses were cervical dystonia (42%), hemifacial spasm (20%), and blepharospasm (9%). Common diagnoses made prior to the movement disorder diagnoses were nerve/muscle problem (33%), stress/psychological problem (39%), tremor (16%), fibromyalgia (14%), TMJ (10%), joint/tendon problem (15%) and spine (10%). The average number of physicians seen before the movement disorder diagnosis was 3.1. Amongst these were family physicians (78%), neurologists (71%), movement disorder specialists (32%), chiropractors (17%), eye care doctors (17%), physiotherapists (17%), and neurosurgeons (10%). Most physicians who made the current movement disorder diagnoses were neurologists (63%) and movement disorder specialists (33%). The average time in years from onset of symptoms to movement disorder diagnosis were: cervical dystonia 6.6, blepharospasm 4.7, hemifacial spasm 3.8, spasmodic dysphonia 2.5, limb dystonia 8.2, Meige syndrome 2.8, generalized dystonia 1.6, oromandibular

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dystonia 2.1. 95% of patients were treated with BoNTA following their movement disorder diagnosis. CONCLUSIONS: The number of physicians seen and length of time from onset to movement disorder diagnoses are considerable. Increased awareness of movement disorders at the primary care level may improve these rates.

DATA ANALYSIS OF PEDIATRIC INPATIENTS DIAGNOSED WITH BRAIN ABSCESS Redd R

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OBJECTIVES: Brain abscess is a somewhat rare condition found more commonly in pediatric patients than young adults. While fatalities as a result of brain abscesses have decreased significantly in recent years, the possibility of the condition being fatal is very real. Early diagnosis and treatment are the keys to effectively resolving the issue. The purpose of this paper is to examine patient outcomes for those diagnosed with brain abscess. METHODS: Data were taken from the National Inpatient Sample (NIS). The data consist of pediatric patients diagnosed with brain abscesses (N = 252) and a randomly selected control group (N = 260). SAS Enterprise Guide, a statistical software program, was used to analyze the data set and provide an overview of the results. Methods used included one-way frequencies, statistical summaries, kernel density estimations, and linear and logistic regression models. RESULTS: Contrary to other sources, the age of pediatric patients in the sample seems to play a role in the likelihood of developing brain abscesses. Factors such as age, gender, and race were shown by several different methods to be not significant in the diagnosis. The mortality rate was found to be five times higher in the treatment group than the control suggesting that while this condition may be declining with respect to deaths, the rate is still significantly higher than a random control group from the NIS database. CON-CLUSIONS: While the mortality rate for brain abscesses is low, current procedures can still be improved to lower the rate further. New techniques of diagnosing brain abscesses can also be developed with the research found in the NIS. Further studies should be performed in order to find more relationships. Finding the connection between these connections may lead to better preventive measures and improved treatments for brain abscesses.

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FACTORS ASSOCIATED WITH HEALTH-RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS RECEIVING NATALIZUMAB

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OBJECTIVES: To assess factors associated with health-related quality of life (HRQoL) in MS patients after three natalizumab infusions. METHODS: MS patients, newly enrolled in the manufacturer's restricted drug distribution program and participating in a longitudinal study of their experiences with natalizumab, complete assessments prior to treatment initiation and after the 3rd, 6th and 12th infusion. HRQoL was assessed with the SF-12v2 where higher physical and mental component summary (PCS and MCS) scores indicated improvement in HRQoL. Univariate, followed by multivariate, linear regression was used to identify factors associated with HRQoL after three natalizumab infusions. The factors used in this analysis include age, clinical characteristics (disease duration, number of prior MS treatments) and baseline (BL) disease severity measures (disease step (DS), functional status, fatigue score, cognitive functioning (CF) score). RESULTS: At the time of this analysis 504 patients had completed BL and 3^{rd} assessments. Mean age was 46.08 ± 10.93, 78% of patients were female, and mean disease duration was 9.64 ± 8.33 years. PCS and MCS scores improved significantly from baseline (PCS: 34.03 versus 36.02; p < 0.001) and MCS: 43.17 versus 47.22; p < 0.001). Multivariate analysis indicated that higher BL PCS scores (p < 0.001), lower BL DS scores (p < 0.001) and younger age (p = 0.002) were associated with improvement in PCS scores after three natalizumab infusions. Similarly, higher BL MCS (p < 0.001) and BL CF scores (p = 0.001) were associated with improvement in MCS scores after the 3rd infusion. CONCLUSIONS: Factors associated with improvement in PCS scores after the 3rd infusion were younger age, higher BL PCS scores, and lower BL DS scores (better ambulation) while those associated with improvements in MCS scores were higher BL MCS scores and higher BL CF scores. These results suggest that initiating natalizumab in younger patients having lower disability and better baseline HRQoL results in greater improvements in HRQoL after three natalizumab infusions.

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PREDICTORS OF PATIENT AND PHYSICIAN-REPORTED SATISFACTION/ EASE-OF-USE RATINGS WITH RASAGILINE IN PARKINSON'S DISEASE Buck PO, Castelli-Haley J, Conner JB

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OBJECTIVES: Parkinson's disease (PD) is a progressive neurodegenerative disorder that affects 1 million people in the United States. Several available treatments are effective in controlling its symptoms; however, relatively little research has examined patient- and physician-reported PD treatment satisfaction/ease-of-use (SEU) ratings. These post-hoc analyses examined whether improvement in PD symptoms and disabilities predicted subsequent ratings of SEU with rasagiline, a selective irreversible monoamine oxidase type-B inhibitor. **METHODS:** The LEGATO trial was an open-label study of 0.5 mg and 1.0 mg once daily rasagiline in PD patients at 38 community-based centers in the United States. Baseline treatment determined patients'

stratification to mono- or adjunct therapy. Outcome variables were patient- and physician-reported treatment SEU ratings at weeks 4 and 12. Predictors included change from baseline in the bradykinesia subscale of the Unified Parkinson's Disease Rating Scale, change from baseline in patient- and physician-reported Activities of Daily Living (ADL), and patient- and physician-reported Clinical Global Impression (CGI). Data were analyzed using linear regression. RESULTS: SEU ratings with rasagiline were positive at all visits. Complete data were available for 109 monotherapy and 131 adjunct therapy patients at week 12. Patient- and physician-reported CGI were positively related to SEU ratings reported by the same individual at the same visit (p < 0.05); patient-reported CGI was positively related to physician-reported SEU ratings at week 4 (p < 0.05). Bradykinesia improvement from baseline predicted physician-reported SEU ratings at week 4 for monotherapy (p < 0.01). Patient-reported ADL improvement from baseline predicted patient-reported SEU ratings at week 12 for adjunct therapy (p < 0.01). CONCLUSIONS: Patient- and physician-reported CGI were consistently related to patient- and physician-reported SEU ratings with rasagiline. Furthermore, improvement in bradykinesia symptoms and patient-reported ADL predicted subsequent ratings of treatment SEU in some cases. Additional research on patient- and physician-reported treatment SEU scales in PD populations is needed to refine this important endpoint.

NEUROLOGICAL DISORDERS - Health Care Use & Policy Studies

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EPIDEMIOLOGIC CHARACTERISTICS AND HEALTH RESOURCE USE IN A MULTIPLE SCLEROSIS CENTER IN SAO PAULO, BRAZIL

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OBJECTIVES: Multiple Sclerosis (MS) is an immunomediated, highly disabling disease affecting young adults. The demographic characteristics, disease modifying therapies and health resources utilization by patients followed at a MS reference center in Sao Paulo, Brazil are presented. METHODS: Patient's charts were reviewed from a retrospective cohort of 353 MS patients. Patients were selected by attendance to outpatient visits at Hospital das Clínicas, Faculty of Medicine - University of Sao Paulo from March to May 2008. RESULTS: From 353 patients, 74% were female and 86% were white-Caucasians. A positive family history was identified in five patients. Sixty-eight percent had relapsing-remitting MS, 13% secondary progressive MS and 10% primary progressive MS. Half of the patients had MS diagnosis for less than 5 years. At the last interview, 226 patients (64%) were on immunomodulatory agents. From these, 59 patients were using glatiramer acetate and 167 were using beta-interferons. The immunomodulatory drug was changed in 11 patients. Sixty-one patients (17%) were on immunossupressants, with 31% using azathioprine. Average EDSS score at last visit was 4.2. Approximately 24% of patients had at least one relapse requiring treatment and 5% were hospitalized in the last 12 months. CON-CLUSIONS: There are few data on epidemiology and health resource use published in Latin-American countries, while many countries like Brazil provide high-cost treatments at public health system. In our study, the current approved MS therapies were widely used. Therefore, the understanding of local patients' characteristics and health resources use can provide data for an optimized, tailored disease management solutions in these countries.

DISEASE BURDEN AND TREATMENT PATTERNS OF PARKINSON'S DISEASE IN A LONG TERM CARE SETTING

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OBJECTIVES: Examine the patient characteristics, treatment patterns and cost of care among Parkinson's Disease (PD) residents in a long term care (LTC) setting, specifically, skilled nursing facilities (SNFs) in the US. PD is a progressive neurodegenerative disorder that produces considerable morbidity. The prevalence and incidence of PD increase with age. PD affects more than 3% of individuals over 65 years old. METHODS: Retrospective analysis of PD patients in SNFs from June 2004-2008. Using a large provider database, 7885 PD patients were identified. Patient demographics, comorbidities, treatment patterns and costs were assessed using administrative and clinical databases at baseline and one year (1 year). RESULTS: A total of 4150 PD patients with baseline and 1 year data constituted the analysis cohort, mean age of 82 years, 46% male and 57% admitted from an acute care hospital. At baseline, 43% had fallen in the past 30 days, 94% reported bathing assistance; 24% and 38% were bladder and bowel continent; 71% and 44% suffered short and long-term memory loss. Patients received speech, occupational and physical therapy for 68, 153 and 157 minutes per week. The average patient had 6 comorbid conditions: hypertension (64%), depression (46%), dementia (43%) and diabetes (31%) were common. 83% were diagnosed with PD before or at SNF admission. At baseline, 79% were PD medication-free; 49% remained PD medication-free over 1y. Patients averaged 11 medications. Concomitant medication use of analgesics, antihypertensives and antidepressants were the most common. Direct LTC monthly medical costs were \$5355 and \$6097 at baseline and 1 year. CONCLUSIONS: PD patients have physical and cognitive impairment, combined with debilitating comorbidities. Falls, incontinence, memory loss, hypertension, depression, dementia and diabetes complicate PD treatment in LTC. Concomitant medication burden further complicates treatment. Ongoing examination into treatment needs and barriers to PD medication use is needed to alleviate PD burden in LTC.

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SOCIOECONOMIC FACTORS OF INSOMNIA PRESCRIPTION IN A NATIONAL DATABASE

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OBJECTIVES: Our study aims to identify socioeconomic factors related to insomnia prescription patterns in US outpatient settings. METHODS: This project proposes a secondary data analysis using a national longitudinal database from 2004 National Ambulatory Medical Care Survey (NAMCS). Study subjects were derived from outpatient visits in which at least one insomnia drug was prescribed. A series of weighted chi-square statistics were performed to compare insomnia drug uses across various physician and patient characteristics. All analyses used SAS statistical software and incorporated sample weights and standard errors correction. RESULTS: Among the 910 million outpatient visits that took place in the US in 2004, an estimated 24. 98 million visits included at least one insomnia drug prescription. The majority of prescriptions were allocated to antidepressants (52.3%), which were more frequently prescribed than non-benzodiazepines (34.1%) and benzodiazepines (13.6%). Differences in drug pricing may explain these findings: the average wholesale price (AWP) for antidepressants is lower (\$0.31) than non-benzodiazepine hypnotics (\$2.52). Patient comparisons by insurance type revealed that Medicaid patients were less likely to receive the relatively expensive non-benzodiazepines (27.55%) than Medicare (32,53%), self-pay (33,39%), and private insurance (35,03%) patients. Prescribing patterns were significantly influenced by physician specialty (P = 0.0001), with general/ family physicians contributing the greatest frequency of insomnia prescriptions (36.1%). Females received significantly more insomnia prescriptions than males (16.4 mil. vs. 8.58 mil.; P < 0.0001) and Black/Hispanics received significantly fewer insomnia prescriptions than did white patients (10.78% vs. 87.13%, P < 0.0001).CONCLUSIONS: Our findings indicate significant socioeconomic disparities in the use of insomnia prescriptions. While drug pricing might account for some of our results, marketing-particularly the sociodemographic and physician characteristics toward which such efforts are targeted-provides another strong explanation for prescription pattern disparities. Further evaluation of current practice guidelines and development of more manageable regulations might ensure greater consistency in treatment patterns.

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DRUG UTILISATION AND EXPENDITURE ASSOCIATED WITH TREATMENTS OF NEUROLOGICAL DISORDERS Tesar T, Foltan V, Binder R

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OBJECTIVES: To analyse the utilisation of drugs for treatment of neurological disorder (ATC group: N01-N07) within Slovakia between 1999 and 2007 and to asses the economic consequences of the medications. METHODS: For 1999-2007, the data about consumption of drugs for treatment of neurological disorder were collected following ATC/DDD methodology. Data of wholesalers, who are legally obliged provide this information to the Slovak Institute for Drug Control, was used for the analysis. The results were expressed in the numbers of the packages, finance units (€) and defined daily doses per 1000 inhabitants per day (DID). RESULTS: The collected data showed a significant increases in consumption of drugs for treatment of neurological disorder from 1999 to 2007 in term of DID (in 1999 (108.92), in 2003 (119.46) and in 2007 (142.57). A large increase in consumption of psychoanaleptics (in 1999 (16.00), in 2003 (33.22) and in 2007 (44.84) and a stable consumption of psycholeptics in 1999 (40.88), in 2003 (38.33) and in 2007 (41.34) in term of DID can be seen from this analysis. We can see a slight increase in consumption of drugs in term of DID within the group of antiepileptics (in 1999 (4.60), in 2003 (5.25) and in 2007 (6.86) and anti-parkinson drugs (in 1999 (3.19), in 2003 (3.81) and in 2007 (3.92). Financial expenditures for psychoanaleptics (in 1999 (€16,613,000), in 2003 (€40,572,000) and in 2007 (€30,382,000), for psycholeptics (in 1999 (€10,504,000), in 2003 (€24,603,000) and in 2007 (€36,502,000) can be seen from this study. CON-CLUSIONS: Inseparable components of the Slovak drug policy must be viewed realistically with regard to the consumption of drugs for neurological disorder. Adherence to principles of neurological treatment's guidelines lead to fundamental short and long term financial savings within health care systems.

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ANTIPSYCHOTIC DRUG USE IN PATIENTS WITH ALZHEIMER'S DISEASE TREATED WITH RIVASTIGMINE VERSUS DONEPEZIL: EVIDENCE FROM HEALTH CLAIMS DATA

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OBJECTIVES: Cholinesterase (ChE) inhibitors, including donepezil and rivastigmine, are standard of care for mild to moderate cognitive impairment due to Alzheimer's disease (AD). The current study investigates whether treatment with rivastigmine is associated with less use of antipsychotics compared to treatment with donepezil. METHODS: A claims analysis was conducted from 01/2004 through 12/2006 using the MedStat MarketScan database. Patients included had continuous insurance coverage, had at least 1 diagnosis of AD, and were newly initiated on either rivastigmine or donepezil after the first AD claim. Patients using memantine or receiving antipsychotics in the time interval of ≥180 days before and 14 days after the first rivastigmine