Health and Wellness Survey (NHWS) in Brazil.. QOL was measured by the physical component score (PCS) and mental component score (MCS) of the Short Form-12 (SF-12). Loss of work/productivity was measured by the validated Work Productivity and Activity Impairment instrument. Medical resource utilization was measured by health care provider, emergency room visits and hospitalization in the past 6 months. **RESULTS:** Of the 12,000 respondents, 215 (1.6%) were identified as AD patient's caregivers where 63.7% were women. The age group with the highest proportion of caregivers was 45-54yrs old (36.2%), and they are significantly older than non-caregivers (44.7 vs. 40.8, $p<0.05$). AD caregivers group reported more specific co-morbidities (insomnia 33.8%, cardiac arrhythmia 20.7%), similar mean scores of PCS (49.8 vs. 49.7) and MCS (47.3 vs. 46.9), similar percentage of emergency room visits (21.5% vs. 21.8%), and similar percentage of hospitalization visits (9.9 vs. 9.8) over the past 6 months compared to the group of not caregivers of AD patients. Furthermore, caregivers of AD patients' group reported 22.3% impairment in daily activity compared to 22.1% in the group of not caregivers of AD patients. **CONCLUSIONS:** From the Brazil NHWS results, AD caregivers suffer from impairment in QOL, work/productivity loss and more specific co-morbidities. Findings indicate there is still an unmet medical need in AD caregivers in Brazil.

PND43

DEVELOPMENT OF THE SATISFACTION WITH INJECTION EXPERIENCE QUESTIONNAIRE FOR PATIENTS WITH MULTIPLE SCLEROSIS

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OBJECTIVES: The majority of currently approved disease-modifying therapies for Multiple Sclerosis (MS) are injectables; however, there is no validated injection satisfaction questionnaire for patients with MS. The Satisfaction with Injection Experience (SIE) questionnaire was developed as a reliable and valid scale to evaluate this critical aspect of MS treatment satisfaction. **METHODS:** The medical literature was reviewed to determine the domains that were relevant to MS injection satisfaction. Five domains were identified, along with the most commonly used response options and recall period. A draft SIE questionnaire was evaluated in cognitive debriefing interviews with MS patients. The final 5-item SIE questionnaire utilized a 2-week recall period, a 5-point Likert scale, and was scored as an unweighted mean composite with higher scores representing greater satisfaction. Preliminary psychometric analyses were conducted using baseline data from ENCORE, a multicenter clinical trial designed to investigate 2 formulations of glatiramer acetate (GA) for subcutaneous injection. Data were analyzed using item-total Spearman correlations, Cronbach's alpha, and principal components analysis. **RESULTS:** Complete data were available for 142 MS patients who had been on the currently marketed 20mg formulation of GA utilizing the autoject 2 for glass syringe for at least 90 days (mean = 4.8 years; SD = 3.6). The mean score on the SIE questionnaire was 4.1 (SD = 0.8; range 1.0 to 5.0). All item-total Spearman correlations were greater than 0.30 (range 0.34 to 0.79) and the SIE questionnaire demonstrated excellent overall internal reliability (Cronbach's alpha = 0.82). Based on the eigenvalues and scree plot of the principal components analysis, a single component was extracted, with 58.6% of total variation explained. **CONCLUSIONS:** The 5-item SIE questionnaire exhibited good psychometric properties, including evidence of reliability and content validity. Furthermore, this sample of MS patients, who were long-term users of GA, reported high levels of satisfaction with their injection experience.

PND44

ASSESSING VARIATIONS IN TRANSITIONS IN EMPLOYMENT IN RELAPSING-REMITTING MULTIPLE SCLEROSIS PATIENTS TREATED WITH EITHER LAQUINIMOD, INTERFERON BETA 1-A OR PLACEBO: EXPOLORATORY EVIDENCE FROM THE UNITED STATES SUBSTUDY OF BRAVO

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OBJECTIVES: To assess in short-term changes in employment status in relapsing-remitting multiple sclerosis (RRMS) patients are treated with either oral, once daily placebo, once daily Laquinimod 0.6mg or weekly intramuscular (IM) injections of Interferon beta 1a. **METHODS:** Patients residing within the United States (n = xx) with RRMS and Expanded Disability Status Scale (EDSS) < 5.5 were randomly assigned to receive Laquinimod 0.6mg once daily, oral placebo once daily or Interferon β-1a 30mcg intramuscular injection weekly in the randomized, placebo controlled BRAVO trial. U.S. patients completed the validated Work Productivity and Activity Impairment Scale-General Health (WPAI-GH) at baseline and every three months thereafter. At study completion, patient's transitions from 1) unemployment to employment; 2) no transition in employment; and 3) transitions from unemployment to employment were assessed using univariate statistics. **RESULTS:** Sixty-two patients residing in the United States completed the WPAI-GH with comparable study populations assigned to each of the three study arms. Statistically significant differences were observed across the three treatment arms when consideration was given to changes in employment status ($p < 0.001$). Seventy-seven percent of patients treated with Avonex reported no change in employment status during the course of the study while 81% of patients in each of the Laquinimod or placebo arm reported no change. Patients enrolled in the Avonex group report the greatest transition from employment to unemployment (18%) compared to Laquinimod (9%) and placebo (6%). **CONCLUSIONS:** Managed care pharmacists consider multiple factors when making formulary decisions. While safety and efficacy are the primary considerations, other factors that influence patients and employers are frequently evaluated. While exploratory in nature, variations in changes in employment status may occur in RRMS patients treated with alternative disease modifying therapies. These findings, however, are preliminary in nature and warrant future consideration through additional research.

PND45

MOBILITY IMPAIRMENT AND HEALTH-RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS

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OBJECTIVES: Emerging data suggest that even mild or subclinical mobility loss associated with multiple sclerosis (MS) may adversely affect health-related quality of life (HrQoL). We evaluated the impact and timing of mobility impairment on HrQoL. **METHODS:** The North American Committee on Multiple Sclerosis (NARCOMS) registry was used to conduct a cross-sectional study of participants who completed the biannual update and supplemental Spring 2010 surveys. The NARCOMS Performance Scale for mobility was used to grade severity of mobility impairment. HrQoL assessments included the Short Form(SF)-12, physical and mental subscales (PCS and MCS), the EuroQoL (EQ)-5D, EQ-Visual Analog Scale (VAS), and SF-6D. **RESULTS:** A total of 3483 registrants completed both surveys. Compared with those rating themselves as "normal" (n=628) on the mobility performance scale, participants describing their disability as "minimal" (n=566), "mild" (n=535), "occasional support usage" (n=535), "frequent cane usage" (n=527), "severe" (n=543), and "total" (n=105) each reported poorer HrQoL scores on the PCS and MCS (PCS range: 53.6-30.5, MCS range: 46.8-40.3; $p<0.001$ for all). The largest relative decrement in PCS and MCS came at the transition from "normal" to "minimal" (PCS: 15.1%, MCS: 6.2%) and "minimal" to "mild" mobility impairment (PCS: 15.4%, MCS: 5.9%), with the detrimental effect of poorer mobility more profound on the PCS, and little effect on the MCS after the earlier stages of mobility impairment. Poorer health utility was also reported in participants in impaired mobility categories compared to "normal" when examined using each of the utility measures (EQ-5D range: 0.89-0.53, EQ-VAS range: 0.83-0.55, SF-6D range: 0.78-0.58; $p<0.001$ for all). The largest decrements in utility came at the transition from "normal" to "minimal" (9.6%-10.3%) and "minimal" to "mild" mobility impairment (an additional 8.6%-10.7%). **CONCLUSIONS:** These data suggest that mobility impairment may negatively affect HrQoL, with the most profound decrements occurring at earlier stages of mobility loss.

PND46

LONGITUDINAL ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE IN AN OBSERVATIONAL COHORT OF PATIENTS WITH CYSTIC FIBROSIS

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OBJECTIVES: To evaluate associations between changes in health status over time and health-related quality of life (HRQOL) using the Cystic Fibrosis Questionnaire-Revised (CFQ-R), a disease-specific patient-reported outcome (PRO) measure of HRQOL. **METHODS:** Using the Epidemiologic Study of Cystic Fibrosis (ESCF) data, we identified participants who had completed age-appropriate CFQ-R assessments on 2 occasions separated by 9 to 15 months. We developed multivariable regression models to test whether associations existed between 1) changes in respiratory signs/symptoms and changes in the respiratory health domains of the CFQ-R; 2) changes in nutritional health status and changes in the nutritional health domains of the CFQ-R; and 3) changes in treatment complexity and changes in the Treatment Burden scale of the CFQ-R. **RESULTS:** We analyzed 1947 pairs of assessments: 337 child (8.9, range 6-13 years), 581 parent (mean age of child 8.8, range 6-13 years), 398 adolescent (mean age 15.3, range 14-17 years), and 631 adult (mean age 26.9, range 18-73 years). On average, we found little change in both health status indicators and CFQ-R domain scores over 1 year. Significant associations over time, however, were found with declining weight and worsening scores on the CFQ-R nutritional health domains, and increases in treatment complexity and worsening CFQ-R Treatment Burden scores for parent respondents. **CONCLUSIONS:** Health status and HRQOL changes were small over a 1-year period in this CF population. Changes in respiratory symptoms and weight, however, were associated with significant changes on relevant CFQ-R scores, indicating that this PRO is sensitive to changes in health status over time.

NEUROLOGICAL DISORDERS – Health Care Use & Policy Studies

PND47

RESCUE MEDICATION USE IN THE ACUTE TREATMENT OF MIGRAINE DURING MAP0004 PIVOTAL TRIAL

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OBJECTIVES: This post hoc analysis evaluated the use of rescue medication in the acute treatment of migraine episodes reported during a randomized, placebo-controlled, double-blind trial of MAP0004, an investigational, orally inhaled dihydroergotamine. **METHODS:** Rescue medication use (RMU) was permitted in this study if migraine symptoms were not relieved 2 hours after study drug administration. RMU in the MAP0004 and placebo treatment groups were adjusted for baseline pain scores and compared according to demographic and baseline disease characteristics (eg, age, gender, race, migraine history, baseline pain severity). The