OBJECTIVES: Daytime functioning is a widely used outcome to describe quality of patients’ functional performance during daytime and gaining popularity as an efficacy outcome in pharmaceutical interventions. The purpose of this study was to conduct a review of the literature and identify studies and patient-reported outcome instruments that purport to measure daytime functioning. METHODS: A search was conducted of the English-language studies published between January 1950 and June 2008 using Medline. Key terms used were ‘daytime function and questionnaires’, ‘daytime functioning and quality of life’, and ‘daytime functioning and quality of life’. Studies that observed functional performance from adult population were exclusively selected and of those articles, patient-reported questionnaires were identified. Validity of instruments was assessed based on reported psychometric properties. RESULTS: Total of 55 articles were identified. Studied patient population had sleep disorders (including apnea) (n = 47), cancer (n = 2), restless leg syndrome (n = 1), allergic rhinitis (n = 1), Alzheimer’s disease (n = 1), coronary artery disease (n = 1), obstructive bladder (n = 1), and Parkinson’s disease (n = 1). Of these, 45% (n = 25) articles included a patient-reported outcome questionnaire that claimed to measure daytime functioning. The remaining articles (55% n = 30) included objective measurement to describe daytime function or used questionnaires without the supporting evidence of reliability, validity and interpretability. METHODS: A total of 55 articles were reviewed. CONCLUSIONS: Not all studies that purport to measure daytime functioning used validated PRO tools to measure changes in daytime functioning. The criteria of defining daytime functioning were differed among different disease states. Future studies that will investigate the domain of daytime functioning, it is recommended to select appropriate validated PRO instruments that can support the intended claim.

OBJECTIVES: To explore the association of baseline health-related quality of life and clinically measured EDSS and T25FW. RESULTS: Results were summarized by Physical Component Score (PCS-12) and Mental Component Score (MCS-12). Analysis of variance methods were used to explore the association of HRQoL and clinical functioning. RESULTS: At higher EDSS scores (i.e., worsening disability), both physical and mental HRQoL were lower; however, this association was only statistically significant for PCS-12 (p < .001 for PCS-12, p = .707 for MCS-12). For PCS-12, among patient EDSS groups, pairwise differences were statistically significant between EDSS 1–2 vs. EDSS 2.5–4.4 (44 vs. 37.2; p = .004), suggesting a marked worsening of physical HRQoL at or above the disability threshold of EDSS 2.5. Both PCS-12 and MCS-12 were higher for the group with better ambulation: T25FW < 7 sec vs. T25FW > 7 sec (43.5 vs. 37.3, p = .006) for PCS-12; 43.9 vs. 41.0, p = .079 for MCS-12). CONCLUSIONS: Physical HRQoL is associated with functional impairment assessed via the EDSS and T25FW. This suggests that the PCS-12 component of the generic HRQoL tool reflects clinical functional impairment in MS patients.

OBJECTIVES: To evaluate the factors driving patient selection of primary medication for multiple sclerosis. METHODS: Baseline data from the Betaseron® Outcomes Study (ROBUST) is a US, prospective, 12-month, observational, single-arm, open-label, multi-center outcomes study of interferon beta-1b given every other day for relapsing forms of MS were analyzed. At baseline, patients were asked to rate the importance of factors that are typically considered before making a decision to select the primary medication to treat MS (on a 0–5 scale) at all important factors were evaluated: how well the medication worked, how much the medication is given per dose, convenience of taking medication, convenience of storing medication, frequency of administration, information in product decision kit, injection needle of the medication, clinical research, doctor recommendation, family opinion, opinion of other MS patients and recommendation of MS advocacy groups. Mean scores on each factor were compared across patient sociodemographic characteristics, primary medication types and disease severity. RESULTS: At baseline, a total of 99 reported taking medication to treat their MS and thus provided responses on the items of interest. In this sample, 80.8% were females, 61.6% married, 70.4% below 50 years old and 82.8% White. Among all patients, the highest importance scores were for how well the medications controls MS progression (Mean [95% Confidence Interval] 4.72 [4.57–4.86]) followed by their doctor’s recommendation (4.57 [4.41–4.72]); the convenience of taking the medications (3.88 [3.63–4.13]), personal research (3.81 [3.56–4.05]) and the convenience of storing the medication (3.71 [3.44–3.98]). These factors and their order of importance remained consistent across sociodemographic characteristics, primary medication types and disease severity. CONCLUSIONS: Contributing to the limited published research about factors considered by patients when selecting primary medication for their MS, this analysis found that medication effectiveness to control MS progression and doctor recommendation are the most important drivers of medication selection.

OBJECTIVES: To evaluate the association of baseline health-related quality of life (HRQoL) and clinical measures of disability and motor functioning in a real-world observational study of multiple sclerosis (MS) patients. METHODS: The Real-World Betaseron® Outcomes Study (ROBUST) is a US, prospective, 12-month, observational, single-arm, open-label, multi-center outcomes study of interferon beta-1b given every other day for MS. A total of 226 patients were registered at 52 neurologists’ sites. Clinical measures and patient outcomes were reported by physicians via a web-based data capture tool. The Kurtzke Expanded Disability Status Scale (EDSS) and Timed 25-foot Walk (T25FW) in seconds) were measured by the neurologist at baseline to evaluate patient disability and motor functioning. HRQoL was measured at baseline for 191 patients via the SF-12 Health Survey. For this analysis, EDSS and T25FW were categorized into five (0, 1–2, 2.5–4, 4.5–5.5, 6) and two (< 7, > 7) groups, respectively. SF-12 results were summarized by Physical Component Score (PCS-12) and Mental Component Score (MCS-12). Analysis of variance methods were used to explore the association of HRQoL and clinical functioning. RESULTS: For multidimensional scores (i.e., worsening disability), both physical and mental HRQoL were lower; however, this association was only statistically significant for PCS-12 (p = .001 for PCS-12, p = .707 for MCS-12). For PCS-12, among patient EDSS groups, pairwise differences were statistically significant between EDSS 1–2 vs. EDSS 2.5–4.4 (44 vs. 37.2; p = .004), suggesting a marked worsening of physical HRQoL at or above the disability threshold of EDSS 2.5. Both PCS-12 and MCS-12 were higher for the group with better ambulation: T25FW < 7 sec vs. T25FW > 7 sec (43.5 vs. 37.3, p = .006) for PCS-12; 43.9 vs. 41.0, p = .079 for MCS-12). CONCLUSIONS: Physical HRQoL is associated with functional impairment assessed via the EDSS and T25FW. This suggests that the PCS-12 component of the generic HRQoL tool reflects clinical functional impairment in MS patients.

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drug treatment, occupational advancement, current work status, and direct cost was detected in univariate analyses. CONCLUSIONS: To our best knowledge this is the first observational study on the burden of GTS in Germany. With annual total costs of about €12,500, GTS places a notable financial burden on society. HRQoL is considerably reduced in patients with GTS. While tic treatment is important, co-morbidities such as depression should be regarded more seriously.

PND39 IMPROVEMENT IN HEALTH-RELATED QUALITY OF LIFE IN MULTIPLE SCLEROSIS PATIENTS ON NATALIZUMAB IN THE UNITED STATES Agarwal S1, Stephenson J2, Hou L1, Kamar S3, Rajagopalan K1
Blegen Idec Pharmaceuticals, Wellesley, MA, USA; HealthCore, Inc., Wilmington, DE, USA; Blegen Idec Pharmaceuticals, Cambridge, MA, USA

OBJECTIVES: To assess patient-reported treatment satisfaction with natalizumab in MS patients treated with natalizumab in a “usual care setting” in the United States (US). METHODS: MS patients starting natalizumab were invited to participate in a 1-year longitudinal health outcomes study assessing their experiences with natalizumab. MS patients complete self-reported assessments prior to natalizumab initiation and after the 3rd, 6th and 12th natalizumab infusions. The current analysis reports the change in general HRQoL assessments using the SF-12v2 from baseline through the 6th natalizumab infusion. Physical and Mental Component Summary (PCS and MCS, respectively) scores were computed at each assessment. PCS and MCS scores range from 0 to 100, with higher scores indicating better HRQoL. The a-priori study hypothesis was that patient-reported HRQoL improves over time with longer duration of natalizumab treatment. Statistical regression models were used to evaluate the effect of natalizumab over time in HRQoL over time after controlling for the number of natalizumab infusions, age, years since MS diagnosis, baseline disease disability and functional status, comorbidity burden, and number of MS drugs used prior to natalizumab.RESULTS: A total of 296 patients were analyzed. The mean age was 47 ± 11 years and the majority of patients were female (78%). The mean number of years since MS diagnosis was 11 ± 9 years. After controlling for covariates, a statistically significant increase (improvement) in PCS scores (BL 34 ± 11, 3rd 36 ± 12 and 6th 36 ± 11; p < 0.0001) and MCS scores (BL 43 ± 12, 2nd 47 ± 11 and 6th 48 ± 13; p < 0.0001) was observed from baseline through the 6th infusion. CONCLUSIONS: Patients reported significant improvements in both physical and mental aspects of HRQoL over 6 months of treatment, suggesting an improved effect of natalizumab over time. These results document the improvement in HRQoL of MS patients receiving natalizumab in the usual care setting and are consistent with clinical study findings.

PND40 PATIENT REPORTED OUTCOMES IN THE EARLY STAGES OF MULTIPLE SCLEROSIS: THE BEGIN STUDY Hagström M1, Spisström M1, Høibol N1, Wicklén EM2, Marito M1, Tintoré M1
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OBJECTIVES: Reports from clinical trials suggest that physical activity (PA) can be beneficial for multiple sclerosis (MS) patients. However, participation in PA was found to be low in MS patients with substantial physical disability. We assessed levels of PA and their interaction with depression and health related quality of life (HRQoL) in early-stage MS patients. METHODS: THE BEGIN study (Betaseron® treatment and Exercise data Gathering IN early MS) is an international prospective observational study of early-stage MS patients, including clinically isolated syndrome suggestive of MS (CIS). Subjects received Betaseron®. PA levels were assessed by the International Physical Activity Questionnaire (IPAQ) and a pedometer, and depression using the Center for Epidemiological Studies Depression Scale (CES-D), and HRQoL with the EuroQol 5 dimension (EQ-5D) utility scale and Visual Analogue Scale (VAS) score. RESULTS: PA data were collected from 609 patients (68.0% women) in 16 countries in Europe, Asia, Australia and Latin America. Mean age was 36.3 years (SD 9.9). The median MET-minutes/week derived from IPAQ at baseline was 3349 (SD 4942). A negative Spearman’s rank correlation was found between the steps per day and depressive symptoms (p = 0.01). Mean depression scores decreased monotonically in higher IPAQ categories. EQ-5D utility and VAS scores were on average 0.7 (SD 0.2) and 71.7 (SD 19.5), respectively. The steps per day showed to be positively correlated with higher VAS (p = 0.01) and utility (p < 0.01) outcomes. CONCLUSIONS: PA in early-stage MS patients was found to be positively associated with HRQoL. Adding the results of the longitudinal data after two years of follow-up may lead to further insights regarding the role of PA in early-stage MS patients and its relation to HRQoL.

PND41 IMPROVEMENT IN PATIENT SATISFACTION WITH INCREASING NATALIZUMAB TREATMENT DURATION IN MULTIPLE SCLEROSIS PATIENTS IN THE UNITED STATES Stephenson J1, Hou L1, Agarwal S1, Rajagopalan K1, Kamar S3
HealthCore, Inc, Wilmington, DE, USA; HealthCore, Inc, Wilmington, DE, USA; Blegen Idec Pharmaceuticals, Wellesley, MA, USA; Blegen Idec Pharmaceuticals, Cambridge, MA, USA

OBJECTIVES: To assess patient-reported treatment satisfaction with natalizumab in MS patients in the United States (US). METHODS: MS patients initiating natalizumab were invited to participate in a longitudinal study. Patients complete self-reported assessments prior to natalizumab initiation and then after the 3rd, 6th and 12th natalizumab infusions. As part of the baseline (BL) assessment, patients reported their satisfaction with MS drugs used prior to natalizumab initiation. For the follow-up assessments, patients reported their satisfaction with natalizumab treatment. Patient self-reported measures included satisfaction with treatment effectiveness, drug treatment, occupational advancement, current work status, and direct cost was detected in univariate analyses. CONCLUSIONS: To our best knowledge this is the first observational study on the burden of GTS in Germany. With annual total costs of about €12,500, GTS places a notable financial burden on society. HRQoL is considerably reduced in patients with GTS. While tic treatment is important, co-morbidities such as depression should be regarded more seriously.

PND42 INTERPRETING SCORES ON THE MULTIPLE SCLEROSIS-SPECIFIC PRIMUS AND U-FIS OUTCOME MEASURES Tanaka A1, Downes C1, McCanna SF2, Barker I1
Cancer Research, Manchester, UK; Novartis Pharma AG, Basel, Switzerland

OBJECTIVES: Estimating the most important difference (MID) of patient reported outcome (PRO) measures is important to guide interpretations of scores and for assessing treatment effect in clinical trials and studies. The current study was designed to estimate the MID of newly developed PROs for Multiple Sclerosis (MS); The Patient Reported Indices for Multiple Sclerosis (PRIMUS; which includes Activity and Quality of Life (QoL) scales) and Unidimensional Fatigue Impact Scale (U-FIS). The measures have been shown previously to be unidimensional, valid and reliable. METHODS: Data were taken from the TRANSFORMS study, a multi-centre clinical trial evaluating the safety and efficacy of oral fingolimod compared to IFNβ-1a i.m. in relapsing-remitting MS patients. PRO assessments were completed at baseline, 6 and 12 months. Measures included the PRIMUS-Activities (scored 0–30), PRIMUS-QoL (scored 0–22), U-FIS (scored 0.0–10.0), EQ-5D and EQ-VAS scales. A high score indicates more severe impact. Both anchor (published EQ-SD MID values) and distribution (0.2 and 0.5 effect sizes, standard error of measurement) based approaches were employed. Anchor-based MID values were assessed both for individual who improved or deteriorated according to EQ-SD MID values. Triangulation results of the obtained MID values for PRIMUS and U-FIS MID estimates. RESULTS: Trial sample: n = 1292, 63.7% female, mean age 36.2 (SD 8.5), mean MS duration 7.4 years (SD 6.2). Anchor and distribution based MID’s ranged from 0.9–2.9 (PRIMUS-QoL, 0.7–2.3 (PRIMUS Activities) and 2.4–7.3 (U-FIS)). Triangulation resulted in the following MID values; PRIMUS Activities 1.5 for individuals improving or deteriorating; PRIMUS QoL 1.5 for individuals improving or deteriorating and U-FIS 4.5 for those improving and 5.0 for those deteriorating. CONCLUSIONS: The analyses provided the preliminary information on the interpretation of scores on the scales. The MID values will aid the assessment of treatment effect in clinical trials and studies.

PND43 ASSOCIATION OF HEALTH-RELATED QUALITY OF LIFE AND RELAPSE IN THE PREVIOUS YEAR AMONG MULTIPLE SCLEROSIS PATIENTS: BASELINE DATA FROM ROBUST Halper J1, Kirzinger S3, Preblick R4, Bi YJ4, Gemmen EK5
MS Center at HNH, Teaneck, NJ, USA; Wake Forest University School of Medicine, Winston-Salem, NC, USA; University of Louisville, Louisville, KY, USA, Bayer HealthCare Pharmaceuticals, Inc; Health Economics, Outcome and Reimbursement (HEOR), Wayne, NJ, USA, Quintiles, Inc; Falls Church, VA, USA

OBJECTIVES: To measure the association of health-related quality of life (HRQoL) and pre-baseline relapse among multiple sclerosis (MS) patients in a real-world observational study. METHODS: The Real-World Betaseron Outcomes Study (ROBUST) is a 12-month, US prospective, observational, open-label, single-arm, multi-center outcomes study of interferon beta-1b given every other day for MS. Analysis of variance methods were used to measure the association of SF-12 Health Survey (SF-12) scores and pre-baseline relapse descriptors (relapse status, frequency, severity of typical and worst relapse). SF-12 results were summarized by Physical Component Score (PCS-12) and Mental Component Score (MCS-12). RESULTS: Both physical and mental scores were lower among patients reporting to be in relapse at baseline (N = 78) than among those reporting to be relapse-free at baseline (N = 115); however, the difference was statistically significant only on the MCS-12 (43.9 vs 48.5; p = 0.045). Reduction of both PCS-12 and MCS-12 were strongly associated with increasing frequency of patient relapses.