Buck PO1, Castelli-Haley J1, White RE1, Rendas-Baum R2, White MK2

health care cost, it seems that the refill-adherence rate of antiparkinson medicine items schedules adds up to aggravation of Parkinson’s disease leading to death and amplified (90%).

and represented 6.5% (n = 4,691) had unacceptable low refill-adherence rates below 90%, that accounted for 41.62% (n = 16,398,512.00) of the total cost (N = R3,402,898.20) of all antiparkinson medicine items included in this study. Only 36.78% (n = 3,235) of antiparkinson medicine items had acceptable refill-adherence rates between 90% and 110%. Those with unacceptable refill-adherence rates accounted for 9.72% (n = 852) of all antiparkinson medicine items and represented 6.5% (n = 252,674) of the total cost. No practical significant difference in the average refill-adherence rates was found between male (93.99% ± 186.99) and female (90.83% ± 175.21) patients. Biperiden, carbidopa/levodopa, and levodopa/benserazide containing products had on average acceptable non refill-adherence rates (<90%). CONCLUSIONS: Although poor obedience to treatment schedules adds up to aggravation of Parkinson’s disease leading to death and amplified health care cost, it seems that the refill-adherence rate of antiparkinson medicine items is not very favourable.

A PSYCHOMETRIC EVALUATION OF THE REVISED SCOPA DIARY CARD IN PARKINSON’S DISEASE PATIENTS

Buck PO1, Castelli-Haley J1, White RE1, Rendas-Baum R2, White MK2

Teva Neuroscience, Kansas City, MO, USA; 2QualityMetric Incorporated, Lincoln, RI, USA

OBJECTIVES: The Scales for Outcomes in Patients with Parkinson’s disease Diary Card (SCOPA-DC) is a daily diary designed to measure motor impairment in Parkinson’s disease (PD) patients with fluctuating symptoms. Previous qualitative research evaluated the content validity of the SCOPA-DC in the US and expanded it to measure non-motor symptoms. The current research examined the psychometric properties of the revised SCOPA-DC. METHODS: A sample of adults age 30 and older with self-reported doctor-confirmed PD were recruited, screened, and consented online from a Knowledge Networks panel. Eligible patients were mailed a study packet that contained the revised SCOPA-DC as well as a training video. The revised SCOPA-DC included 5 items: fatigue, memory, anxiety, pain, difficulty swallowing, frequent urination, and sweating. The diary was completed 7 times per day for 3 consecutive days. Consistent with the original SCOPA-DC, 3-day scores were calculated for each item. Higher scores indicated greater symptom severity. RESULTS: A total of 101 PD patients completed and returned the revised SCOPA-DC. The sample was 50.5% male and had been diagnosed with PD for an average of 7.4 years. Frequency distributions showed little missing data (approximately 1.0%), although items were generally right-skewed. Fatigue (25.4) and walking (28.7) had the highest mean scores; scoring (7.3) and difficulty swallowing (9.7) had the lowest mean scores. Factor analysis supported a 3-factor solution: mobility, physical functioning, and psychological functioning. These factors demonstrated good internal consistency (alpha = 0.83–0.87) and correlations with health-related quality of life instruments were suggestive of construct validity. CONCLUSIONS: In this US sample of PD patients with varied disease severity, the revised SCOPA-DC exhibited good psychometric properties, including evidence of reliability and validity. Furthermore, patients reported that the revised SCOPA-DC was clear and easy to complete. The revised SCOPA-DC holds promise for measuring a broad spectrum of fluctuating motor and non-motor PD symptoms.

COMPARISON OF ANALYTIC HIERARCHY PROCESS AND CONJUNCTIVE ANALYSIS METHODS IN ASSESSING TREATMENT ALTERNATIVES IN STROKE REHABILITATION

Isaacman J1, Bridges JP2, Van Til D3

University of Toronto, Ehsanlou, The Netherlands; Johns Hopkins University, Baltimore, MD, USA

OBJECTIVES: There has been increasing interest novel HTA methods that will incorporate patient preferences in a more transparent and scientifically valid way. The fundamental problem of the assessment of benefits in HTA is the identification, ranking and valuation of multiple health care outcomes. We used two multi-criteria methods to rank and value five different treatments in stroke rehabilitation. Analytic Hierarchy Process (AHP) stems from operations research and is increasingly being used in health care to weigh patient-reported endpoints. Conjoint analysis (CA) is a stated preference method that often takes the discrete choice format. In CA, hypothetical scenarios are used to generate part-worth utilities for attributes. METHODS: To determine the clinical decision context and related criteria, a paper-and-pencil questionnaire was conducted among a sample of Dutch physicists/psychologists in a stroke interdisciplinary group. From the lists of criteria and clinical benefit, two expert panels defined the AHP decision structure and as the conjoint analysis survey format. Finally, the complete questionnaire including the AHP and CA survey was sent out to 184 patients with ankle-foot impairments. Eventually, 89 patients completed both surveys. RESULTS: On average, the prediction of preferred treatment within a group level is similar for both AHP and CA. However, on an individual level there seems to be more variation in treatment preference. Using AHP weights, a vast majority preferred soft-tissue surgery where most patients preferred orthopedic shoes if CA weights were used. This may have been caused by labelling effects of the attributes. CONCLUSIONS: Both methods have their pros and cons in ranking and valuing patient-reported endpoints. Of the methods AHP is relatively easy to apply. In prediction of overall outcome, both methods perform equally. However, for individual treatment preference we observed some differences. It may be concluded that the decision structure, framing and labelling of the treatment attributes are more important than the specific elicitation method used.

HEALTH STATUS COMPARISON BETWEEN STABLE PARKINSON’S DISEASE PATIENTS AND THOSE EXPERIENCING EARLY WEARING-OFF

Buck PO1, White RE1, Castelli-Haley J1, Rendas-Baum R2, White MK2

Teva Neuroscience, Kansas City, MO, USA; 2QualityMetric Incorporated, Lincoln, RI, USA

OBJECTIVES: End-of-dose wearing-off is commonly experienced by Parkinson’s disease (PD) patients who have used dopaminergic therapy for several years. Most investigations of wearing-off have traditionally focused on motor fluctuations, it is increasingly recognized that non-motor symptoms also vary between periods of “ON” (when PD symptoms are minimized due to medication) and “OFF” (when PD symptoms return). This study characterizes the self-reported health status of PD patients who experienced OFF-time as compared to those who were stable. METHODS: Recruited from an online panel maintained by Knowledge Networks, adults with self-reported doctor-confirmed PD were screened, consented, and completed a cross-sectional survey. Frequency of OFF-time was measured using the Disease Rating Scale Part IV. Demographics, PD-specific characteristics, the 9-item Wearing-off Questionnaire (WOQ-9), the Short Form-12v2 (SF-12), and the Parkinson’s Disease Questionnaire-8 (PDQ-8) were also assessed. RESULTS: Data were available for 163 PD patients (mean age = 66.6 years; 52.7% male; mean time from diagnosis = 7.1 years). Twenty-five (15%) of the patients reported experiencing OFF-time on a typical day and were classified as stable; the remaining 85% reported experiencing OFF-time. There were few significant differences between the two groups in terms of demographics and PD history. Compared to those experiencing OFF-time, stable patients reported fewer motor and non-motor wearing-off symptoms based on the WOQ-9 (P < 0.05), as well as better health on the Physical and Mental Component Summary scores of the SF-12 (P = 0.05) and the Summary Index score of the PDQ-8 (P = 0.05). CONCLUSIONS: PD patients who experienced OFF-time on a typical day reported worse overall physical and mental well-being than stable patients. Furthermore, both motor and non-motor wearing-off symptoms differed between the two patient groups. Additional research to understand the consequences of OFF-time would be useful, especially as it pertains to non-motor symptoms.

PATIENT AND PHYSICIAN GLOBAL PERCEPTION OF LEVODOPA/ CARBIDOPA/ENTACAPONE VS. LEVODOPA/CARBIDOPA IN PATIENTS WITH PARKINSON’S DISEASE EXPERIENCING EARLY WEARING-OFF

Rover J1, Batâlia M1, Laboz R1, Hernández B1, Todesa E1

Novartis Farmacéutica S.A., Barcelona, Spain; 2Hospital Clínic de Barcelona, Barcelona, Spain

OBJECTIVES: To compare patients’ and physicians’ global perceptions of Parkinson’s disease (PD) in two treatment groups: levodopa/carbidopa/entacapone (LCE) vs. levodopa/carbidopa (LC). METHODS: Multicentre, double-blind, randomized, phase IV study. Ninety-five PD patients with early wearing-off (WO) and deterioration of activities of daily living (ADLs) were randomised to receive LCE (n = 46) or LC (n = 49) with a 3-month follow-up. Patient and physician global perception of PD was assessed at the end of the study. The PDQ-39 quality of life (QoL) questionnaire, and the longitudinal course of PD using the different parts of UPDRS (part I, part II, part III, and IV) were evaluated along the study. Differences between health improvement by patient and physician were analyzed by the Mann Whitney U-test. The mean differences from baseline to final visit in PDQ-39 and in UPDRS (part I, II, III, IV) scores were analyzed by an ANCOVA model. RESULTS: Mean (SD) age was 66.4 ± 8.6 years and 50.0% were women. Half percent of patients showed stage II according to the Hoehn and Yahr classification. Patient global perception showed a significant better score in the LCE than in LC group (−0.9 ± 1.0 LCE and −1.7 ± 1.7 LC, p = 0.0291). Similar results were obtained by the physician (−0.3 ± 0.8 vs. −0.4, p > 0.05, 0.007). The adjusted mean differences in the PDQ-39 showed a trend for a higher improvement in QoL in the LCE group (6.3 ± 2.04 vs. 8.81 ± 15.66), although did not reach statistical significance. The UPDRS evaluation showed a significant higher
response in part II and III (p = 0.0078 and p = 0.0072, respectively), a trend to better results for the LCE group was observed in part I and IV. CONCLUSIONS: Levodopa/carbidopa/entacapone shows a significant better patient and physician global percep-
tion in the LCE treatment group vs. LC group in PD patients with early WO and AIDs deterioration.

DIFFICULTIES IN IDENTIFYING THE ORIGINAL SOURCE QUESTIONNAIRE FOR USE IN TRANSLATIONS: THE ADAS-COG CASE STUDY
Anfray C1, Giroudet C2, Berne C3, Acquaroz C4
1Mapi Institute, Lyon, France; 2Mapi Research Trust, Lyon, France
STUDY QUESTIONNAIRE FOR USE IN TRANSLATIONS: THE ADAS-COG CASE STUDY
Anfray C1, Giroudet C2, Berne C3, Acquaroz C4
1Mapi Institute, Lyon, France; 2Mapi Research Trust, Lyon, France
OBJECTIVES: Since its development in the 80’s, variations of the Alzheimer’s Disease Assessment Scale-Cognitive subscale (ADAS-Cog), a Clinician-Reported Outcome (ClinRO) measure, have been used to monitor disease progression and treatment efficacy in Alzheimer’s disease. The objective of this study was to identify all versions used as a basis for translation in Mapi Institute projects and to take stock of existing translations.
METHODS: The review was based on all ADAS-Cog translation projects performed by Mapi Institute. RESULTS: Sixteen projects were identified representing a total of 70 languages and 219 translations. Translations were based on 11 source versions which differed in terms of content (number of items, order of items and instructions), and format. The number of items ranged from 11 to 15. Four studies used 13 items, but only in two cases the same items were used although in a different order. Four studies used 12 items: only two studies used the same items (with a different order of list of words for the Word Recognition Task), but again in a different order. Format and instructions differed in all cases. In most projects the source version provided by the sponsor was a single document containing instructions with the rater and response forms. Only in 3 cases the original consisted in a separate instruction manual and response forms. With regard to available translations, more than one translation was identified in 56 of the 70 available languages and in one language (Swedish) as many as 7 translations. CONCLUSIONS: The abundance of different versions of the same questionnaire both in its original US English form as in translations makes comparisons between studies or pooling of data difficult for both researchers and users. In the light of FDA’s recent PRO guidance it would be beneficial to demand the same scientific rigor when using ClinROS in international studies.

RESPONSIVENESS OF THE MULTIPLE SCLEROSIS INTERNATIONAL QUALITY OF LIFE QUESTIONNAIRE TO EXPANDED DISABILITY STATUS SCALE SCORE CHANGES IN PATIENTS WITH MULTIPLE SCLEROSIS: MONTH 12 RESULTS FROM AN INTERNATIONAL OBSERVATIONAL STUDY
Augier P1, Fernandez O2, Bucktzweier H3, Flachenecker P4, Idman E5, Pelletier J6, Stochchi S7, Verduin di Cantogno E7, Issard D7, Simeoni MC
1Timone University Hospital, Marseilles, France; 2Hospital Regional Universitario Carlos Haya, Malaga, Spain; 3Royal Melbourne Hospital, Melbourne, Australia; 4Neurological Rehabilitation Center, Queenenhoef, Bad Vilbad, Germany; 5Dokuz Eylul University, Izmir, Turkey; 6UO Riabilitazione e Scienze Multipa, Bologna, Italy; 7Med. Serra S.A., Geneva, Switzerland
OBJECTIVES: Quality of life (QoL) is an important measure that is often overlooked in the assessment of multiple sclerosis (MS). The MS International Questionnaire (MsQoL) profile is a validated, MS-specific instrument. This study aimed to assess the responsiveness of the MsQoL questionnaire to changes in Expanded Disability Status Scale (EDSS) scores in patients with MS. METHODS: In this ongoing, 24-month, observational study MsQoL and EDSS scores were recorded at baseline (BL) and at 6-month intervals. The primary endpoint is change in MsQoL index score from BL to month 24 (including effect size). Secondary endpoints include change in MsQoL index score from BL to month 12 and change in MsQoL scale scores. RESULTS: Of 600 patients enrolled, 474 had evaluable BL and month-12 EDSS and MsQoL index data. At BL, mean (SD) EDSS score was 2.9 (1.9); mean (SD) MsQoL index score was 68.5 (14.4); and mean (SD) MsQoL scale scores ranged from 3.9 (2.8) to 85.4 (18.5). At month 12, 68 patients (14.3%) had a worse EDSS score than that recorded at BL. Mean (SD) change in MsQoL index score was 0.48 (10.89) overall and −1.00 (9.88) in “worstened” patients. Effect sizes were 0.147. There is a marked gradient on scores by severity and frequency of pain experience. The impact of pain on HRQoL is more significant than the impact of socio-demographic characteristics. Drivers of caregiver’s absolute utility scores. METHODS: The study is based on data from the internet based 2008 National Health and Wellness Survey undertaken in the UK, France, Spain, Germany and Italy. This study identified 11,000 respondents (1 in 5 of the estimated 58 million Europeans who had experienced pain in the last month). The assessment of the quantitative impact of pain status on HROq was estimated via three single equation general linear (ordinary least squares) models which estimate the impact of pain on PCS, MCS and utility scores. The model includes a range of variables which have been shown in previous populations to influence impact on HROq (such as socio-demographic factors, health risk behaviors, comorbid conditions, medication utilization, duration of medication utilization and satisfaction with care). The experience of pain is captured by a combination of severity and frequency categorical variables. VARIABLES: Pain has a substantial impact on all three of the dimensions of HROq. CONCLUSIONS: The magnitude of the impact of pain is more significant than the impact of socio-demographic characteristics. Risk factors, comorbidities and the experience of pain medication. CONCLUSIONS: The presence of moderate and severe pain imposes a significant burden on persons reporting pain in the 5 EU countries; the burden increases the greater the frequency and severity.

THE RELATIONSHIP BETWEEN SOME INDICATORS INFLUENCING THE QUALITY OF LIFE OF PEOPLE WITH DOWN’S SYNDROME LOOKED AFTER IN THE FAMILY AND PARENTAL QUALIFICATION IN CONNECTION WITH A STUDY CARRIED OUT IN HUNGARY
Harjáné Brantmiller E, Pláti O1, Pál K1, Nagy I1, Krizsabáth I1, Boneza F2, Sándor J3
1University of Pécs, Pécs, Hungary; 2University of Debrecen, Debrecen, Hungary
OBJECTIVES: The aim of the study was to survey some subjective and subjective indicators determining the quality of life of people with Down’s syndrome (DS), born between 1975 and 2005, looked after in their families in the Southern-Transdanubian region of Hungary. The relationship between the parental level of education and the above factors was explored. METHODS: On the basis of the VRESYS database (National Registry of Congenital Anomalies) health visitors contacted families looking after DS people (N = 107), and conducted anonymous, questionnaire surveys in 2008-2009. Reading was examined from school-age (N = 79), drawing and writing was examined depending on age. RESULTS: The abilities under examination moved

QUALITY OF LIFE OF CAREGIVERS IN HUNTINGTON’S DISEASE—FIRST RESULTS FROM EURO-HBD STUDY
Devypré C1, Clay E2, Aubeluck A3, Vermy C3, Abelaia S4, Squitieri F5, Tournier M6
1Crémy Deval, Deval, France; 2University of Lyon, France; 3University of Lyon, France; 4Neurogenetics and Rare Disease Centre, Pozzi, Italy; 5University Claude Bernard Lyon 1, Lyon, France
OBJECTIVES: Huntington’s disease (HD) is a rare neurodegenerative disease leading to profound disability for patients and poor quality of life (QoL) for patients as well as caregivers. This study investigated the impact of HD on caregivers’ QoL and its drivers. METHODS: The European HD burden study (Euro-HBD) is an ongoing cross-sectional survey among HR patients and their caregivers in six countries (France, Italy, Germany). The Huntington’s disease Quality of Life Battery for Carers (HDQol-C) short-version, a previously validated questionnaire by Aubeluck A. and Buchanan H., was administered. Pearson correlations with generic HDQol-C scores and the specific HRQOL in HD for patients (HDIQol2) were evaluated. The determinants of caregiver QOL among drivers among patients’ clinical characteristics (voluntary movement disorders, chorea, depression/anxiety, psychotic disorder, cognition, temper) were studied by regression analysis adjusting on age, sex and occupational categories. The relationship between QOL of patients and caregivers were also explored. RESULTS: Up to date, 201 caregivers in France and 124 in Italy have been enrolled. For France (respectively Italy) 6% (12%) were completely satisfied by their overall QOL and 7% (5%) were totally satisfied. HDQol-C scores were poorly correlated with generic caregiver HRQol-C correlation equaled 0.31 for EQ3D utility and varied between 0.04 and 0.45 for the eight domains of SF36. Correlation was quite high (0.59; p < 0.01) between HDQol-C and Hqol2. Drivers of caregivers’ QoL were voluntary movement disorders (p = 0.049), depression/anxiety (p = 0.02), psychotic disorder (p = 0.01) and cognition (p = 0.01). Temper and chorea were not drivers of caregivers’ QoL independently of other clinical characteristics. CONCLU-
sions: Caregivers HDQOL worse in the patient clinical characteristics especially voluntary movement disorders, depression/anxiety, psychotic disorders and caregivers Disorders. Patients and caregiver Qol was indirectly correlated via patient clinical scores. The potential impact on caregiver QOL should be considered in evaluations of innovative HD treatments.

THE IMPACT OF PAIN SEVERITY AND FREQUENCY ON HRQOL IN THE BIG 5 EUROPEAN UNION COUNTRIES
Landyas PC1, Liolagas H2
1University of Minnesota, Minneapolis, MN, USA; 2Grunenthal GmbH, Aachen, Germany
OBJECTIVES: This study assesses, for an estimated EU pain population of 50 million patients, the impact of pain severity and frequency on three dimensions of health related quality of life (HRQoL): the SF-12 MCS and PCS scores and (ii) the SF-6D absolute utility scores. METHODS: The study is based on data from the internet based 2008 National Health and Wellness Survey undertaken in the UK, France, Spain, Germany and Italy. This study identified 11,000 respondents (1 in 5 of the estimated 58 million Europeans who had experienced pain in the last month). The assessment of the quantitative impact of pain status on HRQod was estimated via three single equation general linear (ordinary least squares) models which estimate the impact of pain on PCS, MCS and utility scores. The model includes a range of variables which have been shown in previous populations to influence impact on HRQol (such as socio-demographic factors, health risk behaviors, comorbid conditions, medication utilization, duration of medication utilization and satisfaction with care). The experience of pain is captured by a combination of severity and frequency categorical variables. VARIABLES: Pain has a substantial impact on all three of the dimensions of HRQol. CONCLUSIONS: The magnitude of the impact of pain is more significant than the impact of socio-demographic characteristics. Risk factors, comorbidities and the experience of pain medication. CONCLUSIONS: The presence of moderate and severe pain imposes a significant burden on persons reporting pain in the 5 EU countries; the burden increases the greater the frequency and severity.