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 perception in the LCE treatment group vs. LC group in PD patients with early WO and ADLs deterioration.

DIFFICULTIES IN IDENTIFYING THE ORIGINAL SOURCE QUESTIONNAIRE FOR USE IN TRANSLATIONS: THE ADAS-COG CASE STUDY
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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 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 form. 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 SCOLIOSIS 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
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OBJECTIVES: Quality of life (QoL) is an important measure that is often overlooked in the assessment of multiple sclerosis (MS). The MS International QoL (MusIQoL) questionnaire is a validated, MS-specific instrument. This study aimed to assess the responsiveness of the MusIQoL questionnaire to changes in Expanded Disability Status Scale (EDSS) scores in patients with MS. METHODS: In this ongoing, 24-month prospective observational study MusIQoL and EDSS scores were recorded at baseline (BL) and at 6-month intervals. The primary endpoint is change in MusIQoL index score from BL to month 24 (including effect size). Secondary endpoints include change in MusIQoL index score from BL to month 12 and change in MusIQoL scale scores. RESULTS: Of 600 patients enrolled, 474 had evaluable BL and month-12 EDSS and MusIQoL index data. At BL, mean (SD) EDSS score was 2.9 (1.9); mean (SD) MusIQoL index score was 68.5 (14.4); and mean (SD) MusIQoL scale scores ranged from 59.9 (24.8) 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 MusIQoL index score was 0.08 (10.99) overall, and −1.00 (9.88) in “worstened” patients; effect sizes were 0.03 and −0.08, respectively. Changes from BL to month 12 in MusIQoL scale scores were mostly small. However, there were large (mean [SD]) decreases in some subscales at month 12 for “worstened” patients: Activities of daily living− (“Activities of daily living” [18.07]; “Relationships-with-family” [ −5.14 [23.43]]; “Sensitonal-and-sexual-life” [ -4.11 [17.56]; and ‘Relationship-with-health-care-system’ [ -3,56 [14.11]]. Effect sizes were −0.12, −0.25, −0.14 and −0.21 respectively. Conversely, the mean (SD) change in Symptoms score was 5.36 (17.27) at month 12 for “worstened” patients (effect size: 0.24). CONCLUSIONS: As expected, most MusIQoL scores decreased over 12 months in patients with worsening EDSS scores, indicating poorer QoL and confirming the utility of the MS-specific MusIQoL in rating QoL.

QUALITY OF LIFE OF CAREGIVERS IN HUNTINGTON’S DISEASE—FIRST RESULTS FROM EURO-HDB STUDY
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OBJECTIVES: Huntington’s disease (HD) is a rare neurodegenerative disease leading to substantial 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-HDB) 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 HD-QOL (SF36, EQ5D) and the specific HR-QOL in HD for patients (HQQOL) 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: To date, 201 caregivers in France and 124 in Italy have been enrolled. For France (respectively Italy) 6% (12%) were substantially satisfied by their overall QOL and 7% (5%) were totally satisfied. HDQoL-C scores were poorly correlated with generic caregiver HR-QOL; correlation equalled 0.31 for EQ5D 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 HQQOL. 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. CONCLUSIONS: Caregivers HDQoL worsen with the patient clinical characteristics, especially voluntary movement disorders, depression/anxiety, psychotic disorders and cognition disorders. Patients and caregiver QoL was indirectly correlated via patient clinical scores. The potential impact on caregiver QOL should be considered in evaluatons of innovative HD treatments.

THE IMPACT OF PAIN SEVERITY AND FREQUENCY ON HRQOL IN THE BIG 5 EUROPEAN UNION COUNTRIES
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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 3 of the estimated big 5 EU countries) who had experienced pain in the last month. The assessment of the quantitative impact of pain status on HRQOL is 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. These include pain characteristics, socio-demographic factors, health risk behaviors, comorbidity status, 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. RESULTS: Pain has a substantial impact on all three of the dimensions of HRQOL (SF36, EQ5D) measure, have been used to monitor disease progression and treatment especially voluntary movement disorders, depression/anxiety, psychotic disorders and cognition 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 RELATIONSHIP BETWEEN SOME INDICATORS INFLUENCING THE QUALITY OF LIFE OF PEOPLE WITH DOWN’S SYNDROME LOOKED AFTER IN THE FAMILY AND PARENTAL QUALIFICATION IN HUNGARY
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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 VRDS 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