measurement experts to generate items, responses, and instructions for the new scale. Cognitive interviews were conducted with an additional 15 idiopathic RLS patients (aged 25-68) to ensure understanding of the new measure, concept comprehensiveness, and to identify any necessary revisions to the items and conceptual framework. **RESULTS:** Twenty-three items were generated from patient quotes obtained during the concept elicitation interviews. Impacts on next day functioning spontaneously attributed to disturbed sleep due to RLS symptoms included: activities of daily living (i.e., work, household chores), cognitive functioning (i.e., concentration, forgetfulness, mental tiredness, alertness), emotional functioning (i.e., irritability, depressed mood), physical functioning (i.e., physical tiredness, active leisure activities), energy, daytime sleepiness, and social functioning (i.e., relationships, social activities/situations). Concept saturation was achieved. Modifications to questions and responses were based on feedback provided during cognitive interviews. The final measure consists of 14 items assessed "today" and rated on a severity numeric rating scale. CONCLU-SIONS: The RLS-NDI is an evaluative tool with demonstrated content validity to assess the impact of disturbed sleep due to RLS symptoms on RLS patients' next day functioning.

REFINING THE MEASUREMENT OF MOTOR AND NON-MOTOR SYMPTOMS IN PARKINSON'S DISEASE PATIENTS WITH FLUCTUATING SYMPTOMS

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OBJECTIVES: Parkinson's disease (PD) is the second most prevalent neurodegenerative disorder in the US. The Scales for Outcomes in Patients with Parkinson's disease Diary Card (SCOPA-DC) is a daily diary designed to measure motor impairment in PD patients with fluctuating symptoms. Consistent with the FDA's final guidance on patient-reported outcome measures, this study aimed to evaluate the content validity of the SCOPA-DC in the US and determine the feasibility of adding items that measure non-motor symptoms using qualitative techniques. METHODS: A literature review identified the most dominant non-motor symptoms experienced by PD patients with fluctuating symptoms. Three focus groups were conducted with PD patients (n = 24) to identify themes that specifically addressed the study objectives. The original SCOPA-DC was modified based on findings from the literature review and patient input. A fourth focus group (n = 9) consisted of a cognitive debriefing of the revised SCOPA-DC that included additional items and modified structure based upon the previous results. RESULTS: Findings from the focus groups demonstrated support for the content of the original SCOPA-DC, generally finding it to be clear and intuitive, despite difficulties with some item definitions, time frames, and response labels. With respect to non-motor symptoms, seven domains were consistently mentioned: fatigue, concentration/memory, anxiety, pain, difficulty swallowing, frequent urination, and sweating. The cognitive debriefing focus group reported that the revised SCOPA-DC format was easier to use, provided better focus on the items and time frames, and more adequately captured experiences throughout the day as compared to the original. CONCLUSIONS: Non-motor symptoms occur frequently in PD patients with fluctuating symptoms and have a significant impact on health-related quality of life. A reliable and validated patient-reported daily diary may improve the ability to describe PD progression by accurately measuring both motor and non-motor symptoms. Additional quantitative research is needed to evaluate the psychometric properties of the revised SCOPA-DC.

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VALIDATING USE OF THE MIGRAINE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE VERSION 2.1 (MSQ) ACROSS MIGRAINE DISORDERS Elson CL¹, Maglinte GA², Rendas-Baum R³, DeRosa M³, Yang M³, Varon SF²

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OBJECTIVES: To provide evidence for the reliability and validity of the Migraine-Specific Quality of Life Questionnaire Version 2.1 (MSQ) for use across migraine disorders. METHODS: Cross-sectional data were collected via web-based survey in nine countries/regions. Participants were classified per ICHD-2 criteria as having chronic migraine (CM, ≥15 headache days/month), high-frequency episodic migraine (HEM, 10-14 headache days/month), or low-frequency episodic migraine (LEM, ≤9 headache days/month). Three MSQ domains Role Function-Preventive (RP), Role Function-Restrictive (RR), and Emotional Function (EF) were rescaled to 0-100, where higher scores indicate better health-related quality of life (HRQOL), and analyzed for internal consistency reliability (Cronbach's alpha), construct validity (correlations assessed between MSO scales and measures of depression/anxiety [Patient Health Questionnaire; PHQ-4], disability [Migraine Disability Assessment Questionnaire; MIDAS], and functional impact [Headache Impact Test; HIT-6], where lower scores indicate better HRQOL for each), as well as discriminant validity across migraine groups. RESULTS: A total of 8726 eligible respondents were classified as follows: 5.7% CM (n = 499), 5.9% HEM (n = 515), and 88.4% LEM (n = 7,712). Migraineurs were mostly female (83.5%) with a mean (±SD) age of 40.3 ± 11.4, similar across the groups. MSQ domain scores for CM, HEM, and LEM groups respectively were: RP = 61.4 ± 26.1, 65.9 ± 23.8, and 72.1 ± 23.9; RR = 44.4 ± 22.1, 48.3 ± 22.8, and 57.0 ± 24.1; EF = 48.3 ± 28.1, 57.8 ± 27.7, and 67.8 ± 26.5. Internal consistency of the total sample for RP, RR, and EF was 0.90, 0.96, and 0.87, respectively. Similar values were observed across migraine groups. Varied by domains and migraine groups, MSO scores correlated moderately to highly with scores from the

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PHQ-4 (r = -0.28 to -0.47), MIDAS (r = -0.42 to -0.58), and HIT-6 (r = -0.55 to -0.71). Known groups validity indicated significant differences (p < 0.0001) in the hypothesized direction between CM, HEM, and LEM for RP (F = 58.74), RR (F = 91.78), and EF (F = 153.38). CONCLUSIONS: The MSQ is a reliable and valid questionnaire that can differentiate the functional impact between CM, HEM, and LEM.

CONFIRMATORY FACTOR ANALYSIS AND DIFFERENTIAL ITEM FUNCTIONING ANALYSIS OF THE MIGRAINE-SPECIFIC QUALITY OF LIFE QUESTIONNAIRE VERSION 2.1 IN CHRONIC MIGRAINEURS <u>Rendas-Baum R¹</u>, Maglinte GA², DeRosa M¹, Yang M¹, Varon SF²

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OBJECTIVES: The Migraine-Specific Quality of Life Questionnaire Version 2.1 (MSQ) is a 14-item health-related quality of life instrument that measures the functional impact of migraine across three domains: Role Function-Preventive (RP), Role Function-Restrictive (RR), and Emotional Function (EF). This study evaluated the factor structure and cross-cultural comparability of the MSQ in Chronic Migraine (CM) sufferers. METHODS: Cross-sectional data were collected via web-based survey, across eight countries. Respondents were classified as having CM per ICHD-2 criteria with \geq 15 headache days/month (n = 499). Confirmatory factor analysis (CFA) of the 3-factor model was conducted using the robust maximum likelihood estimator (MLR) assuming multivariate normality. Goodness-of-fit was assessed by the comparative fit index (CFI), Tucker-Lewis Index (TFI), and root mean square error of approximation (RSMEA). Differential item functioning (DIF) was tested using ordinal logistic regression of MSQ item scores on group membership and trait level explanatory variables. Groups were based on country (Australia, Canada, Germany, Spain, France, Great Britain, Italy, United States) and language (English/non-English). Nonuniform DIF (significant interaction term between group membership and trait level, p<0.05) and uniform DIF (>10% change in the trait level coefficient resulting from removal of the group membership term from the model) were identified. RESULTS: The 3-factor model demonstrated good fit (CFI = 0.97; TFI = 0.96; RMSEA = 0.07) among CM sufferers. Factor loadings ranged between 0.72 and 0.89, and had similar values across the three factors. Most MSQ items showed absence of DIF. Non-uniform country DIF was identified in items 5 (inability to concentrate; p = 0.028) and 12 (fed up or frustrated; p = 0.037). Item 12 also presented non-uniform DIF related to language (p = 0.010). CONCLUSIONS: Among Chronic Migraineurs, the MSQ provides a valid measure of RP, RR, and EF, yielding domain scores that can be reliably compared across languages and countries.

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CROSS CULTURAL EVALUATION OF THE SHORT FORM 8 ITEM PARKINSON'S DISEASE QUESTIONNAIRE: RESULTS FROM AMERICA, CANADA, JAPAN, ITALY AND SPAIN

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OBJECTIVES: Increasingly health status measures, used to measure the subjective functioning and well being of respondents, are being used in trials of treatments which are undertaken in a variety of countries. The purpose of this study was to evaluate the psychometric properties of a short form health survey, the Parkinson's Disease Questionnaire (PDQ-8), cross-culturally, by comparing results gained from this instrument to the original longer form instrument-the PDQ-39. METHODS: Data are from the Global Parkinson's Disease Survey (GPDS) a cross national survey which utilised the thirty nine item Parkinson's Disease Questionnaire (PDQ-39) as a major outcome measure. In this study, we evaluate results from the PDQ-8 (Single Index Score PDQ-8-SI) with results from the parent form (from which the PDQ-8 was derived), of the instrument in the USA, Canada, Spain, Italy and Japan. RESULTS: We evaluate response rate (97% of the 819 respondents completed all items on PDQ-8), data quality, score reliability (internal reliability of the eight items of the PDQ-8 was calculated for all countries using Cronbach's alpha, USA = 0.88; Canada = 0.83; Italy = 0.87; Spain = 0.79 and Japan = 0.73) and scaling assumptions of the instrument in the USA, Canada, Spain, Italy and Japan. CONCLUSIONS: The evidence suggests that PDQ-8-SI seems a useful measure in studies where a short measure, providing an overall index of self perceived health in PD, is required. The PDQ-8 is a practical and informative instrument for the evaluation of overall quality of life of PD patients in cross-cultural studies.

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AN ASSESSMENT OF DISEASE-SPECIFIC HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS RELATING TO BLADDER DYSFUNCTION USED IN PATIENTS WITH MULTIPLE SCLEROSIS

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OBJECTIVES: Bladder dysfunction is a common symptom in patients with multiple sclerosis (MS). This study assessed the current literature regarding instruments that have been used to measure the health-related quality of life (HRQOL) impact of this chronic illness, and to what extent bladder dysfunction affects HRQOL in this population. **METHODS:** Two searches using MEDLINE/PubMed's MeSH database were made. Ouality of life was isolated by checking the psychology subheading within the