A712

CORE

VALUE IN HEALTH 18 (2015) A335-A766

health related information. RESULTS: Of the 3,571 individuals 2,593 were employed and 978 unemployed, among the latter 27,6% because of health reasons. As consequences of health disturbances 4.9% of the individuals in the employed group could not work any longer in their learned profession, 9.3% could not perform all elements of their jobs, 11.4% had to take breaks more often and 4.1% needed special tools for compensate of their handicaps. These four items were combined with the sick leave information into an "Occupational Disability Index (ODI)". Reliability analysis resulted in Cronbach's alpha of .66 which is fairly satisfactory for a fiveitem index. The ODI correlated well with health measures: General Health (SF-36) by r=.356 (p<.000), Functional Limitation (SF36) r=.398 (p<.000); as well as with measures r=.356 (p<.000). ures of social and economic life-quality: Satisfaction with work r=-.261 (p<.000), Satisfaction with life as a whole r=-.277 (p<.000) and Satisfaction with income r=-.163 (p<000). CONCLUSIONS: The short five-item "Occupational Disability Index" has satisfactory psychometric properties. It can be used to analyse the impacts of diseases on work performance and/or the need for rehabilitation measures.

PRM168

SURVEY OF NEUROLOGIST'S CURRENT PRACTICES IN EVALUATION OF MULTIPLE SCLEROSIS TO IDENTIFY DOMAINS FOR A NEW CLINICIAN-REPORTED MEASURE

Phillips GA1, Matza LS2, Stewart KD2, Coyne KS2, Malley K2 ¹Biogen Idec Inc., Cambridge, MA, USA, ²Evidera, Bethesda, MD, USA

OBJECTIVES: An online survey was conducted with neurologists to understand how they assess multiple sclerosis (MS) during typical office visits. This information was gathered to support the possible development of outcome measures for patients with MS. METHODS: A web-based survey was conducted with neurologists in the United States (US), United Kingdom (UK), Germany, and Sweden in April and May 2015. The survey asked about neurologists' professional background; perceptions of important symptoms and impact; and assessment methods used for each domain. RESULTS: A total of 72 neurologists (26 US; 25 UK; 11 Germany; 10 Sweden) completed the survey, including general neurologists (n=19; 26.4%) and neurologists specializing in MS (n=53; 73.6%). The following signs/symptoms of MS were considered important to assess in every or most office visits by $\geq 75\%$ of the sample: walking/gait issues (87.%), fatigue/exhaustion/tiredness (81.9%), pain (80.6%), bladder (79.2%), coordination (79.2%), weakness (79.2%), balance (77.8%), vision (77.8%), cognition (77.8%), spasticity (77.8%), and mood/emotions (75.0%). Areas of impact most commonly identified as important to assess during office visits included mobility (91.7%), activities of daily living (84.7%), independence (84.7%), work (84.7%), self-care (77.8%), sleep (76.4%), and social functioning (75.0%). Across all signs, symptoms, and areas of impact, the most common assessment approaches were asking the patient a direct question, the neurological exam, and informal observation of the patient. Performance-based measures were used less frequently, most commonly to assess walking (by 23.6% of the sample). Standardized clinician-reported (ClinRO) and patient-reported outcomes (PRO) instruments appear to be used rarely, but most commonly for assessment of cognition (12.5%). CONCLUSIONS: Neurologists reported that MS symptoms are typically assessed via general questions, a neurological exam, and direct observation. According to this sample, standardized measurement approaches are not commonly used. A brief clinician-reported measure of MS symptoms and impact could help standardize and quantify these assessments.

PRM169

PSYCHOMETRIC VALIDATION OF THE MULTIDIMENSIONAL DYSPNEA PROFILE (MDP) QUESTIONNAIRE

Gilet H^1 , Pignier C^2 , Aguilaniu B^3 , Devillier P^4 , Didier A^5 , Perez T^6 , Similowski T^7 , Morélot-Panzini C8

¹Patient-Centered Outcomes - Mapi, Lyon, France, ²Pierre Fabre Médicament, Castres, France, ³Université Joseph Fourier, Grenoble, France, ⁴UPRES EA220, Hôpital Foch, Suresnes, France, ⁵Pôle des Voies Respiratoires, Hôpital Larrey, CHU de Toulouse, Toulouse, France, ⁶Clinique des Maladies Respiratoires, Centre Hospitalier Régional et Universitaire de Lille, Lille, France, ⁷AP-HP, Groupe Hospitalier Pitié-Salpêtrière Charles Foix, Service de Pneumologie et Réanimation Médicale, Paris, France, ⁸Sorbonne Universités, UPMC Univ Paris 06, INSERM, UMRS1158, Paris, France

OBJECTIVES: Dyspnea is a major issue for patients suffering from respiratory diseases. The MDP questionnaire was developed as a tool to evaluate both the sensory and emotional dimensions of dyspnea. The MDP still needed to be validated in a clinical setting context. The aim of this study was to validate the psychometric properties of the MDP. METHODS: A prospective, multicenter and observational study was conducted in patients with chronic obstructive pulmonary disease (COPD) at three times of assessment (inclusion visit, 3 and 3.5 months after) in France. The MDP includes 11 items (1: unpleasantness; 5: sensory dimension and 5: emotional dimension) to compute the immediate perception score (sensory and unpleasantness items) and the emotional score (emotional items). The construct validity (using multi-trait), the concurrent and clinical validity (tested by comparison with MMRC, CAT, SF-12, DIRECT, K6, MCS, HADS and clinical parameters), internal consistency reliability and test-retest reliability allowed assessing the psychometric properties of the MDP. **RESULTS:** The main population included 276 patients (mean age=58, 78.4% male) with COPD at different severity stages. All sensory and emotional items met both convergent and discriminant validity criteria, confirming the structure of the questionnaire. Psychometric scores matched standards for clinical validity (the worse the health status of the patient, the worse the scores; more impacted from GOLD stage $\ensuremath{\mathsf{II}}$ to $\ensuremath{\mathsf{IV}}$ and from MMRC grade 3 to 4), concurrent validity (majority of correlations between 0.40 and 0.70), internal consistency reliability (Cronbach's alpha=0.89 and 0.82 for sensory and emotional dimensions, respectively) and test-retest reliability (intraclass correlations=0.84 and 0.86 for immediate perception and emotional scores, respectively). CONCLUSIONS: The MDP questionnaire is a valid and reliable instrument to measure both sensory and emotional dimensions of dyspnea perceived by COPD patients in a clinical setting context. Further studies will be necessary to evaluate the responsiveness of the questionnaire.

PRM170

HOW FRENCH SUBJECTS DESCRIBE WELL-BEING FROM FOOD AND EATING HABITS? DEVELOPMENT, AND SCORING DEFINITION OF THE WELL-BEING RELATED TO FOOD QUESTIONNAIRE (WELL-BFQ©)

Guillemin I¹, Marrel A¹, Arnould B¹, Capuron L², Dupuy A³, Ginon E⁴, Layé S⁵, Lecerf J⁶, Prost M⁷, Rogeaux M⁸, Urdapilleta I⁹, Allaert FA¹⁰

¹Patient-Centered Outcomes - Mapi, Lyon, France, ²Laboratory of Nutrition and Integrative Neurobiology - NutriNeuro; INRA UMR 1286, Bordeaux, France, ³CERTOP UMR CNRS 5044, $Toulouse, France, {}^{4}Laboratory for \ Experimentation \ in \ Social \ Sciences \ and \ Behavioral \ Analysis$ (LESSAC) ESC, Dijon, France, 5 INRA UMR 1286, Bordeaux, France, 6 Institut Pasteur de Lille, Lille, France, ⁷LARA SPIRAL, Couternon, France, ⁸DANONE Nutricia Research, Palaiseau, France, ⁹Social Psychology Laboratory of Paris (LAPPS EA 4386), Saint-Denis, France, ¹⁰CEN Biotech/CEN Nutriment, Dijon, France

OBJECTIVES: To develop and validate an instrument assessing well-being associated with food and eating habits in a general healthy population, suitable for future food allegation support. Providing well-being and maintaining good health are two main objectives subjects seek from their diet. To date validated questionnaires measuring well-being in the specific context of food in general population do not exist. METHODS: Thorough standardized methodology was followed. Qualitative data from 24 discussion groups conducted with healthy subjects (n=102) and subjects with digestive, joint or immunity complaints (n=96) served to develop the core of the Well-Being related to Food Questionnaire (Well-BFQ). Preliminary validation was conducted with 444 subjects with balanced diet (n=81), non-balanced diet (n=65), or standard diet (n=298). Principal component analyses (PCA) and exploratory factor analyses were performed sequentially to reduce the number of items and determine the questionnaire structure. Confirmatory factor analyses with multi-trait analyses were carried out to confirm its structure. RESULTS: The validated structure of the Well-BFQ has a modular backbone composed of "Grocery shopping", "Cooking", "Dining places", "Commensality", "Eating and drinking" and "Eating habits and health". Each module is measured in terms of food behaviour and benefits: immediate, (Pleasure, Security, and Relaxation); direct and short term (Digestion and Satiety, Energy and Psychology); deferred (Metabolism, Mood and energy, Ageing, Bowel movement, Immunity and Mobility). PCA defined 33 interpretable subscales and 15 single items. Internal consistency reliability of dimensions was very good (Cronbach's alpha: 0.75-0.95). Item convergent validity and divergent validity were moderate to excellent. CONCLUSIONS: The Well-BFQ is unique to assess the full picture of well-being related to food and eating habits in terms of immediate, direct and short and deferred benefits in general population. Its modular structure allows interdisciplinary users to address their specific research (including experimental, cross-cultural comparison studies) needs by selecting the module(s) relevant to their objectives.

MEASURING PREFERENCE-BASED PATIENT BENEFIT OF MEDICAL DEVICES: A NEW INSTRUMENT FOR HEALTH ECONOMIC ASSESSMENTS

Lesén E, Björholt I, Ingelgård A, Olson F

Nordic Health Economics, Gothenburg, Sweden

OBJECTIVES: There is a need for a standardised method for measuring patients' perceived benefit of medical devices. Currently available instruments are either too crude, or applicable only to a specific disease or product. Our objective was to develop a general instrument that measures preference-based patient benefit of medical devices, applicable in health economic assessments of any type of medical device used by patients with any type of disease/disability. METHODS: The development of the instrument followed standard qualitative and quantitative procedures. Interviews with health care personnel within a wide range of disease areas were conducted. General attributes of patient benefit with relevance for various diseases and for various medical devices were identified from the interviews. To refine and test the instrument, these general attributes were validated among health care personnel, patient organizations, manufacturers of medical devices, and in two pilot studies (n=119, n=260) in the general population. In the final step, questionnaires are administrated to a sample of the general Swedish population and analysed using a statistical weighting algorithm to assess the relative importance of each attribute. RESULTS: The development process resulted in an instrument including 24 general attributes related to patient's perceived benefit of medical devices within the following domains: sense of security, social participation, integrity, convenience and useability. Preliminary results indicate that the attributes with highest preference concern reliability, and sense of control of the disease/disability. Facilitation of overnight travelling and storage convenience are considered less important. Attributes concerning social acceptability are of higher importance to younger than to older persons, while simplicity in using the device is more important to older persons. CONCLUSIONS: A novel instrument for measuring patient benefit of medical devices has been developed. This instrument may be used in health economic assessments of various medical devices used in a wide range of diseases.

MODELLING METHODS FOR EQ-5D – A FITTING TIME FOR CHANGE

Reddy B1, Adams R1, Barry M1, Kind P2, Walsh C3, Salomon J4

¹National Centre for Pharmacoeconomics, Dublin, Ireland, ²HSE University, St Petersburg, Russia, ³University of Limerick, Limerick, Ireland, ⁴Harvard University, Boston, MA, USA

OBJECTIVES: Despite EQ-5D's long establishment, valuation methods have only in recent times been subjected to fresh consideration, mainly driven by the introduction of EQ-5D-5L. However, methods in relation to modelling of health states not directly valued have undergone less change. This work uses the Irish 3L data set to test a number of alternative methods for the 3L sets. METHODS: Existing methods employed for valuation studies include fitting logistic regression models to the data. The addition of interaction terms to capture any extreme health problems (N3), moderate levels (D2), and others, has predominated. Using TTO, a respondent may trade off at some unknown point between two given figures. We have applied an interval regression model to ensure that the results take into account such uncertainty. Further we have employed latent variable models to identify subgroups of respondents within the dataset. A reference group can then be identified, rather than excluding respondents according to arbitrary decision rules. RESULTS: A latent variable approach was found to accommodate heterogeneity in the respondent cohort, providing better sensitivity compared to medians (which might otherwise be expected to fulfil a similar role). Interval regression (both log-normalised and otherwise) appears to have only had a small impact on the subsequently derived quality of life in each health state, though it may be considered a more accurate result. The log-normalised interval regression approach also reduced the effect of extreme WTD scores. CONCLUSIONS: We have explored alternative statistical techniques for tackling some of the challenges associated with TTO data. The use of simple regression analysis may not necessarily be the most accurate reflection of population preferences. Techniques such as interval regression and latent variable models should be further investigated in future.

PRM173

DEVELOPMENT OF A DISCRETE CHOICE EXPERIMENT TO ASSESS PATIENTS' AND PROFESSIONALS' PREFERENCES FOR HOME ENTERAL NUTRITION

Olveira G^1 , Martinez Olmos MA^2 , Fernández de Bobadilla B^3 , Ferrer M^4 , Virgili N^5 , Vega B^6 , Blanco M^7 , Layola M^7 , Lizan L^8 , Tribaldos de Suarez M^8

¹Hospital Regi^onal Universitario de Málaga, Malaga, Spain, ²Hospital Universitario de Santiago de Compostela, Spatin, ³Hospital General Universitario de Ciudad Real, Ciudad Real, Spain, ⁴Hospital Clínico Universitario Virgen de Arrixaca de Murcia, Murcia, Spain, ⁵Hospital Bellvitge, Barcelona, Spain, ⁶Hospital Universitario Ramón y Cajal, Madrid, Spain, ⁷Nestle health science, Barcelona, Spain, ⁸Outcomes 10, Castellon, Spain

OBJECTIVES: The aim of this study is to develop and nourish a discrete choice experiment according to the conjoint-analysis systematic development procedures that would allow assessing patients' and professionals' preferences for the characteristics of home enteral nutrition (HEN) via tube feeding, and the concordance of answers between patients and their caregivers in Spain. METHODS: Different attributes and levels were extracted from the published literature and presented to two focal groups formed by patients receiving HEN (n=5) and HEN experts (n=6). Both groups were asked to identify which attributes and levels were relevant when choosing a HEN product, according to their personal or professional experience. In addition, the focal group of patients had to assess if the drafting of those attributes and levels would be intelligible for other patients. A fractional factorial analysis using the support.CEs package for the statistical software R was performed to define the scenarios that would be used on the questionnaire. **RESULTS:** From all the characteristics presented to focal groups, participants identified 6 attributes as relevant, including 2 levels $each: TOLERANCE\ (easily/hardly\ tolerable), ADAPTATION\ TO\ COMORBIDITIES\ (adapt-property) and tolerable and t$ able/not adaptable to other present comorbidities), NUTRIENTS AND CALORIES (provides/does not provide the nutrients and calories needed by the patient), CONTAINER CHARACTERISTICS (its characteristics make easier/harder to handle the packaging), CONNECTIONS BETWEEN THE CONTAINER AND THE FEEDING TUBE (product connections are easy/hard to perform) and INFORMATION (the container includes/does not include information about the nutrient composition and branding). From the 64 possible scenarios, the fractional factorial analysis generated 8 sets of choices that fulfilled the properties of orthogonality and balance. CONCLUSIONS: The first steps of the conjoint-analysis systematic development procedure, has allowed to describe the final HEN characteristic of importance for patients and professionals that later on will produce each scenario utility values.

PRM174

MEASURING THE IMPACT OF SECONDARY PROGRESSIVE MULTIPLE SCLEROSIS (SPMS) IN THE ASCEND TRIAL: EQUATING THE MSIS-29, MSWS-12, ABILHAND-56 AND SF-36

Cano S¹, Cleanthous S¹, Marquis P², Hobart J³, Naoshy S⁴, Mikol D⁴, Petrillo J⁴, Steiner D⁴, Watson C⁴

 1 Modus Outcomes, Stotfold, UK, 2 Modus Outcomes, Newton, MA, USA, 3 Plymouth University, Plymouth, Devon, UK, 4 Biogen, Cambridge, MA, USA

OBJECTIVES: ASCEND is a phase 3, randomized, double-blind, placebo-controlled trial assessing whether natalizumab slows disability progression in SPMS. The objective of this study was to carry out an empirical post-hoc analysis of ASCEND blinded baseline data to equate items from the Multiple Sclerosis Walking Scale (MSWS-12), Multiple Sclerosis Impact Scale (MSIS-29), ABILHAND-56, and Short-Form 36 (SF-36) in order to provide a clearer understanding of the relationship between their respective items on "Physical" and "Psychosocial" impact measurement continua. METHODS: MSWS-12, MSIS-29, ABILHAND-56, and SF-36 data from 889 patients were combined based on a predefined conceptual framework (contrasting broad domains of physical and psychosocial impact). Rasch Measurement Theory (RMT) analyses were performed on the equating item banks using RUMM2030 software to examine: scale-to-sample targeting, item fit, local dependency, and reliability. RESULTS: The 'Physical Impact' item bank showed adequate scale performance except for some reversed thresholds (5 of 92) and misfit (5 of 92 fit residuals; 20 of 92 Chi-square). Relative item locations implied that, in general, lower limb related items represent the less impacted end of the continuum followed by upper limb related items; general limitations items tended to sit in the middle of the measurement continuum. The 'Psychosocial Impact' item bank performed psychometrically well, except for some misfit (7 of 15 fit residuals; 2 of 15 Chi-square). Relative item locations implied that 'worries' and 'anxieties' are at the less impacted end of the continuum followed by 'mood' and 'depression' items. These findings are consistent with clinical expectation. CONCLUSIONS: Psychometrically, the 'Physical Impact' and 'Psychosocial Impact' equating item banks proposed have strong measurement properties. However, issues related to response options and item fit still require consideration (in both banks), and coverage could still be improved in the 'Psychosocial Impact' equating bank due to the relatively small number of items.

PRM175

WHAT DO WE MEAN WHEN WE TALK ABOUT "U.S. SPANISH"?

Towns L¹, Cassedy C², Johnson H², Anderson H³

¹ICON Plc, Oxford, UK, ²ICON Plc, Durham, UK, ³ICON PLC, Oxford, UK

OBJECTIVES: Identify the make-up of the Spanish-speaking population in the United States; assess the impact of immigration on language; analyse issues faced during linguistic validation of Clinical Outcomes Assessments (COA). METHODS: We investigated population numbers of native-Spanish speakers in the US; researched statistics regarding country-of-origin; reviewed linguistic validation projects for the U.S. and Latin America (LATAM); compared the results. RESULTS: The 2010 census revealed that 16% of the U.S. population were of Hispanic or Latino origin, with 13% $\,$ of children under five years old speaking a form of Spanish at home. We discovered that the distribution of Spanish speakers varies according to country of origin, with pockets of high densities. For example, regionally, the South is home to the majority of South American Hispanics (42%), the West is home to 51% of Mexicans, and the Northeast has welcomed over three quarters of Dominican Republicans in the U.S.. $His panies of \, Mexican \, origin \, have \, the \, highest \, population \, of \, Spanish-speakers \, in \, the \,$ U.S. but those of South American and other Central American origins have markedly increased since 2000. There are significant differences in terminology used across Spanish-speaking populations. One example of this variation is the use of 'once every other day', a common instruction for COA or medication administration. The various translations used LATAM included 'one day yes and one day no', 'take once a day on alternating days' and 'every third day'. This diversity demonstrates the number of influences on the U.S. Spanish language due to the varied population, but is only the tip of the iceberg. **CONCLUSIONS:** We recommend that, during linguistic validation, a specific translation is developed for use in the U.S. by working with linguists from a range of LATAM countries. This will ensure a neutral translation is created that will be acceptable to the diverse range of Spanish-speaking individuals throughout the U.S.

PRM176

DEVELOPMENT OF A PREFERENCE-BASED INSTRUMENT: COMPARED WITH EQ-5D

Park J¹, Ahn J¹, Jo M², Shin S¹, Suh J¹, Cho S¹, Ock M², Lee H²

¹National Evidence based Health-care Collaborating Agency, Seoul, South Korea, ²University of Ulsan College of Medicine, Seoul, South Korea

OBJECTIVES: Our study aims to investigate any additional domain more specific to Asian countries while retaining the existing domains of EQ-5D centered on Western society. After identifying candidate domains, we examined the level of health in a general population and compared the results from EQ-5D with additional domains and the ones from original EQ-5D. METHODS: We organized candidate domains that could be included in the preference-based HRQoL instrument after reviewing the HRQoL measures and conducted focus group discussion (FGD) targeting the general public. To examine the practicality of the HRQoL measure, we conducted the survey with nationally representative 1,000 adults aged 19 to 69 in Korea. In order to assess the influence of each domain on HRQoL, we performed quantile and logistic regression analyses using the visual analog scale (EQ-VAS) and self-rated health as a dependent variable. RESULTS: As the result of FGD, vision, hearing, speaking, memory, sleep, vitality, happiness, and close relationship were established as additional measurement domains. Through survey, the mean EQ-VAS score was 80.11 (standard deviation 12.84). Among those who did not have problems in the EQ-5D's 5 domains, the number of people who reported problems in vitality was 244 (37.2%), happiness 130 (19.8%), and sleep 71 (10.8%). Among them, the number of people who described their self-rated health from "good" to "poor" was as high as 76 (11.6%). In the quantile regression model, pain/discomfort and anxiety/depression from the EQ-5D domains and vision, sleep, vitality, and happiness from the additional domains showed statistical significance. Also, the explanatory powers increased. Among the additional 8 domains, the group with vitality, sleep and happiness had a higher probability of having good self-rated health. CONCLUSIONS: Vitality, sleep and happiness were significant additional factors for new HRQoL domains. However, since many other factors may exist outside of HRQoL domains, various aspects should be considered when developing a new tool.

PRM177

ASSESSMENT OF CONTENT EQUIVALENCE AND USABILITY BETWEEN THE PAPER AND ELECTRONIC VERSIONS OF THE PSORIASIS SYMPTOM AND SIGN DIARY (PSSD) AMONG SUBJECTS WITH PLAQUE PSORIASIS

Eremenco S^1 , McQuarrie K^2 , Brooks A^1 , Landrian A^1 , Maguire S^3 , Shepherd P^2 , Han C^2 ¹Evidera, Inc., Bethesda, MD, USA, ²Janssen Global Services, LLC, Raritan, NJ, USA, ³ERT, Boston, MA. USA

OBJECTIVES: To assess content equivalence and usability between paper and electronic versions of the Psoriasis Symptom and Sign Diary (PSSD) on a handheld (24-hour recall) and tablet (7-day recall) among subjects with plaque psoriasis. METHODS: A cross-sectional, qualitative study was conducted involving one-on-one cognitive and usability interviews in US adults with physician-confirmed plaque psoriasis. Each participant completed the 24-hour version on paper and handheld and the 7-day version on paper and tablet, before being interviewed. Participants were randomized to order of recall period and mode administration. Interviews were conducted in two rounds with revisions made to both devices between rounds. RESULTS: The mean age of sample (N=14) was 51 (range: 32 to 73 years); 57% were female. The majority (n=12, 86%) reported positive overall impressions of the handheld and tablet, finding them easy to use and more convenient than paper. Participants also found the PSSD content similar between versions. In Round 1, all participants (n=7) suggested increasing the size of the NRS scale, questions or instructions on the handheld; 4 participants selected a different response than intended due to small scale size. For the tablet, suggestions included increasing the font size and highlighting selected responses. As a result of Round 1, the font size of the PSSD was increased on the handheld, the tablet was updated to highlight the response selected in a different color, and additional