

the health utility associated with NeuP remains unclear. Knowledge regarding this association is needed, as it impacts economic evaluations of treatments for NeuP. **OBJECTIVES:** To undertake a systematic review and meta-analysis of published health utility values of patients with NeuP. **METHODS:** A detailed search of bibliographic medical databases (Medline, Embase, Cochrane Library) and specialist economic databases (NHS Centre for Reviews and Dissemination Economic Evaluation Database and Health Economics Evaluation Database) was undertaken (to September 2008). Reference lists of retrieved reports were also searched. Studies reporting utility single-index measures (preference based) in NeuP were included. Random effects meta-analysis was used to pool utility estimate across studies. The association of utilities and a number of pre-defined factors (NeuP indication, patient age, sex, duration and severity of pain and method of utility scoring) was examined using meta-regression. **RESULTS:** Twenty three studies reporting utility values in patients with NeuP were included, of which 11 were randomised trials that also reported the treatment change in utility. The weighted pooled mean utility score across the studies was 0.48 (95% CI: 0.44 to 0.53). There was evidence of substantial statistical heterogeneity across studies ( $P < 0.0001$ ). Although we found little evidence of variation in utility across patient characteristics or NeuP indication, increasing pain severity was found to be strongly associated with a reduction in utility. **CONCLUSIONS:** This study confirms that NeuP patients experience low utilities and therefore poor quality of life. Pain severity appears to be a major driver of the negative health impact of NeuP and therefore needs to be considered in future economic evaluations of interventions for this patient population.

PSY37

#### THE OBESITY TRENDS IN GENERAL POPULATION OF THE REPUBLIC OF SERBIA

Tadic I<sup>1</sup>, Tasic L<sup>1</sup>, Djekic S<sup>2</sup>, Rakic M<sup>3</sup>, Tasic D<sup>4</sup><sup>1</sup>University of Belgrade, Faculty of Pharmacy, Belgrade, Serbia and Montenegro, <sup>2</sup>Velefarm A.D, Novi Sad, Serbia and Montenegro, <sup>3</sup>Public Pharmacy NIS, NIS, Serbia and Montenegro,<sup>4</sup>University of Utah, Salt Lake City, UT, USA

**OBJECTIVES:** It is known the obesity increases in general population of the Republic of Serbia; the average value of the BMI in adults was 26.0 and 26.7 (2000 vs. 2006). Proposed study, conducted in 2007 had been focused on the dietary behavior and consumption of dietary supplement among the adults, as well as gender differences. **METHODS:** An observational, prospective study was performed among adults (both, males and females) in form of short questionnaire. The questionnaire included 14 topics covering the following concepts: personal data, usage and knowledge of dietary supplements and other way for weight loss. A total of 993 adults were included, 224 (22.56%) who used dietary supplements and 769 (77.44%) who didn't. The study was conducted in public pharmacy setting of three cities of Serbia (Belgrade, Novi Sad and Nis). **RESULTS:** The mean value of BMI for male was 26.25 and female 23.79, difference was statistically significant. It is showed the BMI values were higher in all age groups of males compared to those of females, except in 60 years of age and older. In both cohorts groups the obesity became clinically significant in population older than 40 years of age. Of 224 examinees, only 10% used dietary supplements every day and 12% used it sparingly. The main purpose of their usage is improvement of physical appearance (49%), disease prevention (41%) and existing disease (10%). Previously to dietary supplements use the examinees tried to lose weight through diet (35%), exercise (24%), lower food portions without any diet (23%), more water consumption (11%), and 7% did not take any action. **CONCLUSIONS:** We conclude the outcomes of the proposed study have showed the somewhat awareness and behavior toward obesity in domain of disease prevention and gender difference (males have higher BMI values) exist in the general population of the Republic of Serbia.

PSY38

#### VALIDATION OF THE TREATMENT RELATED IMPACT MEASURE FOR PRESCRIPTION WEIGHT LOSS MEDICATION IN OBESITY; TRIM-WEIGHT

Brod M<sup>1</sup>, Hammer M<sup>2</sup>, Kragh N<sup>2</sup>, Lessard S<sup>1</sup>, Bushnell D<sup>3</sup><sup>1</sup>The BROD GROUP, Mill Valley, CA, USA, <sup>2</sup>Novo Nordisk A/S, Bagsvaerd, Denmark, <sup>3</sup>Health Research Associates, Inc., Mountlake Terrace, WA, USA

**OBJECTIVES:** Obesity is a worldwide pandemic with serious health implications including increased risk of cardiovascular disease and type 2 diabetes. Unfortunately, attempts to develop antiobesity medications have had mixed results due to poor tolerability and adverse events. Furthermore, the absence of a well developed patient reported outcome (PRO) measure assessing the impact of antiobesity medication on functioning and well-being has limited our understanding of treatment impact. This study validated the Treatment Related Impact Measure (TRIM)-Weight, a disease-specific PRO measure for assessing these relevant impacts. **METHODS:** The 43-item TRIM-Weight, developed and debriefed in a previous study according to the 2006 draft FDA guidelines, was validated in this web-based survey in 4 countries (United States, UK, Australia, Canada) for measurement structure and psychometric properties to assess factor structure, reliability, validity for the total score and for each domain. **RESULTS:** Two hundred eight respondents completed the survey. Twenty-one of the 43 items were omitted due to redundancy with other items, ceiling effects, poor factor loadings, or poor conceptual fit resulting in a 22 item measure. A five-factor structure was achieved with domains of Daily Life, Weight Management, Treatment Burden, Experience of Side Effects, and Psychological Health. Internal consistency coefficients of the total score and each subscale ranged between 0.71 and 0.94 and test-retest reliability ranged from 0.75 to 0.86. All pre-specified hypotheses for convergent and the majority for known-groups validity were met. The completion time was estimated to be 3.38 (SD 2.49) minutes. **CONCLUSIONS:** The development of the TRIM-

Weight was conducted according to well-defined scientific principles. The total score, as well as each domain subscale, are a brief, conceptually sound, rigorously developed PRO measure with strong evidence supporting the psychometric properties. Use of the TRIM-Weight in both clinical and research settings can facilitate development of patient-centered treatments resulting in a greater adherence, tolerability, and treatment efficacy.

PSY39

#### LINGUISTIC VALIDATION OF THE LUPUS QOL QUESTIONNAIRE INTO 13 LANGUAGES

Handa ML<sup>1</sup>, McKown S<sup>1</sup>, Gawlicki M<sup>2</sup><sup>1</sup>Corporate Translations, Inc, Chicago, IL, USA, <sup>2</sup>Corporate Translations, Inc, East Hartford, CT, USA

**OBJECTIVES:** Patients with Systemic Lupus Erythematosus (SLE) have shown significantly improved survival rates, causing researchers and physicians alike to become increasingly interested in patients' health-related quality of life. A variety of questionnaires exist to assess this measure; however, the Lupus Quality of Life Questionnaire (LupusQoL) is the only disease-specific questionnaire. Since this questionnaire was only recently developed and psychometrically validated, it has yet to be linguistically validated for use across diverse cultures and languages. The objective of this study was to create and validate thirteen translations of the LupusQoL. **METHODS:** To evaluate the linguistic validity of harmonized translations of the LupusQoL, bilingual (target language and English) interviewers cognitively debriefed subjects to assess their ability to paraphrase and understand the instructions, questions and responses within each translation. A total of thirteen translations were debriefed as part of this research [Chinese (Taiwan), Dutch (Belgium), English (US/Canada), French (Belgium/France, Canada), Greek (Greece), Hungarian (Hungary), Italian (Italy), Portuguese (Brazil), Spanish (Argentina/Chile, Mexico, US/Canada), Swedish (Sweden)]. The results of the debriefings were compared on the basis of comprehension and number of suggested changes. **RESULTS:** Seventy-three subjects were interviewed, between 5 and 7 subjects for each of the 13 languages tested. Subjects ranged in age from 19-76 years, with a mean age of 44.2 years and were stratified by educational level, including participants both with and without a high school degree. The overall item comprehension rate for the LupusQoL was 99.5%. Intra-item and intra-language comprehension rates were also established. All items had a comprehension rate of greater than 91.8%, while most had 100%; all countries had at least a 98.1% rate. **CONCLUSIONS:** The translations of the instrument in this study demonstrated a high level of overall linguistic validity. This research will facilitate inter-country comparisons of Systemic Lupus Erythematosus and the pooling of data in multi-country studies.

PSY40

#### FEASIBILITY OF DAILY DIARIES WITH QOL ASSESSMENT IN CONGENITAL HEMOPHILIA PATIENTS WITH ALLOANTIBODY INHIBITORS

Wilke CT<sup>1</sup>, Young GA<sup>2</sup>, Cooper DL<sup>3</sup>, Pickard AS<sup>4</sup><sup>1</sup>University of Illinois at Chicago, Chicago, IL, USA, <sup>2</sup>Children's Hospital of Los Angeles, Los Angeles, CA, USA, <sup>3</sup>Novo Nordisk, Inc., Princeton, NJ, USA, <sup>4</sup>College of Pharmacy, University of Illinois at Chicago, Chicago, IL, USA

**OBJECTIVES:** Congenital hemophilia (CH) results from a deficiency of factors VIII or IX, and is associated with bleeding. Treatment can be complicated by potential development of alloantibodies (inhibitors), which can result in more difficult to control bleeding episodes and decreased quality of life (QoL) for the patient and family. Prior studies have only assessed QoL at the start and end of a treatment interval. This study reports the preliminary feasibility of evaluating the yet unknown day-to-day QoL variability in CH patients with inhibitors. **METHODS:** Patients with CH with inhibitors or their caregivers were asked to participate in a 90-day diary study that captured all bleed treatments, daily activities, QoL (modified EQ-5D health state classifier, health and pain visual analog scales (VAS)), family anxiety/stress, and activity changes. Patients/caregivers kept primary diaries on paper with optional internet-based data entry. Graphical and quantitative representations were used to assess feasibility and discriminative validity of daily QoL assessment and impact of bleeds on QoL. **RESULTS:** Patients who fully completed the diary study (n = 3) each experienced 4-5 bleeds during diary days (n = 273 total days). QoL patterns were distinctly different across patients (VAS 1-way ANOVA,  $p < 0.001$ ). VAS (Health, Pain) appeared more sensitive to daily variability than EQ-5D dimensions. Health and pain VAS and self-care, usual activities, pain/discomfort, anxiety/depression dimensions discriminated between combined bleed and non-bleed days ( $p < 0.05$ ). Family anxiety/stress and activity changes were more pronounced in the patients with variable baseline QoL suggesting concern over impending bleeds. **CONCLUSIONS:** Preliminary evidence suggests the VAS is a discriminative tool for bleeds for some patients, but a large study will help to further validate the measure at the group level. Daily QoL assessments may be valuable in assessing treatment interventions in patients with CH with inhibitors. Continuation of the study to completion with the planned 35 patients is warranted.