(41.4 versus 46.4, $p = 0.01$), while there was no difference in MCS scores. Results from the regression analysis showed one predisposing variable (unemployment), one enabling variable (income < $0000), and three need variables (increasing number of co-morbidities, severe joint pain, and severe motion limitation) were significantly associated with a lower PCS (model Adjusted $R^2 = 0.38$, $p < 0.0001$). No significant association was found between MCS scores and any variables from the model. **CONCLUSION:** Patients with hemophilia had a lower PCS, whereas MCS was comparable to the general U.S. population. Unemployment, low income, increasing number of co-morbidities, severe pain, and joint impairment negatively impacted HRQoL. Preserving joint health by preventing joint bleeding and arthropathy is important to maximize HRQoL in patients with hemophilia.

PSY39

HEALTH-RELATED QUALITY OF LIFE OF PATIENTS WITH HEMOPHILIA AND INHIBITORS

Lee WC[1], Brown M[2], Joshi AV[3], Foster T[2], Pashos CL[2]
[1]Abt Associates Inc, Bethesda, MD, USA, [2]Abt Associates Inc, Lexington, MA, USA, [3]Novo Nordisk Inc, Princeton, NJ, USA

OBJECTIVE: Health-related quality of life (HRQL) of hemophilia patients with inhibitors has not been well documented in the United States. This study aimed to measure the HRQL of hemophilia patients with inhibitors and compare findings with the HRQL of the U.S. general population. **METHODS:** Hemophilia patients with inhibitors (N = 90) who had participated in a patient forum were mailed a survey which included the SF-12, a validated generic HRQL instrument. Data were analyzed using the standard SF-12 algorithms. Scores were assessed for each of the eight HRQL domains and the two component summary scores Physical (PCS) and Mental (MCS). These were compared to those of the general population. **RESULTS:** Respondents (n = 45, response rate = 50%) were predominantly male (96.1%), and mean age was 20.7 years (SD = 18.8). The majority is hemophilia type A (88.5%) and consider their disease "serious." Mean PCS of respondents was significantly worse (i.e., lower) than that of the general U.S. public (39.9 vs. 49.6: $p < 0.01$). Four domain scores were significantly lower among respondents compared to the general U.S. public: physical functioning, role physical, bodily pain and social functioning ($p < 0.01$). Mean MCS was comparable, 49.9 vs. 49.6 ($p = 0.72$). **CONCLUSION:** These findings confirm results previously shown in Europe (Gringeri et al 2005), that hemophilia patients with inhibitors have a severely impaired physical HRQL, but maintain a normal mental score compared with the general population in the United States.

PSY40

SYSTEMATIC REVIEW OF THE PSYCHOMETRIC PROPERTIES OF THE FUNCTIONAL ASSESSMENT OF CANCER THERAPY—ANEMIA (FACT-AN) FOR ANEMIC CANCER PATIENTS

An JJ[1], Gwadry-Sridhar F[2]
[1]University of Southern California, Los Angeles, CA, USA, [2]University of Western Ontario, London, Ontario, Canada

OBJECTIVE: Anemia is a prevalent condition in patients who are under treatment for cancer. Having an instrument that can assess the impact of this potentially debilitating condition is relevant to the patient and health care provider. Our objective was to evaluate the psychometric properties of the FACT-An for anemic cancer patients. **METHODS:** A comprehensive literature review was performed to summarize the psychometric properties of the FACT-An and its subscales including the FACT-Fatigue and the FACT-General for anemic cancer patients. Published papers and abstracts were retrieved by searching Medline 1992–2007, the Cochrane Library and related websites. Relevant articles cited from these search findings were also reviewed. Key search terms included: anemia, neoplasm, quality of life and erythropoetin. **RESULTS:** Of 272 citations, thirteen articles were included for critical review. Nine papers reported satisfactory internal consistency (Cronbach's alpha = 0.79–0.96) for all subscales except for non-fatigue subscale (0.59–0.79). However, only two studies reported adequate test-retest reliability (Intraclass correlation coefficient = 0.82–0.90). There was acceptable criterion validity with significant ($p < 0.05$) correlations (r = 0.18–0.40) between the instrument and hemoglobin (Hb) levels. Each domains of the FACT-An showed acceptable convergent validity with Piper Fatigue questionnaire (r = 0.52–0.79) and Multidimensional Fatigue Symptom Inventory (r = 0.49–0.89) and showed divergent validity with Marlow-Crowne instrument, which measured the social desirability (r = 0.04–0.18). The significant ($p < 0.05$) differences in the FACT-An scores between the patients who had high Hb levels and low Hb levels showed satisfactory discriminative validity. Minimally important differences ranged 4.24–7.0 were examined using anchor based method, distribution based method and regression analysis. The acceptable responsiveness to change (effect 0.32 for the FACT-An; standardized response mean = 0.39 and Guyatt's responsiveness = 0.55 for the Fatigue subscale) were investigated. **CONCLUSION:** The FACT-An demonstrated overall acceptable psychometric performances as a discriminative and evaluative instrument for anemic patients, although evidence could be strengthened with further research.

PSY41

PATIENT- AND CAREGIVER-REPORTED PREFERENCES FOR CHARACTERISTICS OF TREATMENTS FOR HEMOPHILIA PATIENTS WITH INHIBITORS

Lee WC[1], Brown M[2], Joshi AV[3], Foster T[2], Pashos CL[2]
[1]Abt Associates Inc, Bethesda, MD, USA, [2]Abt Associates Inc, Lexington, MA, USA, [3]Novo Nordisk Inc, Princeton, NJ, USA

OBJECTIVE: Treatment preferences of patients with hemophilia and inhibitors have not been well documented. This study sought to identify treatment attributes most important from a patient/caregiver perspective in the United States. **METHODS:** A discrete choice experiment was conducted to elicit treatment preferences. Hemophilia patients with inhibitors or their caregivers completed a written survey that elicited preferences for treatment features and levels synthesized from the medical literature such as: risk of viral transmission, rise in inhibitor titer, reduction in thromboembolic events, number of infusions, preparation time, infusion time/volume, time required to stop bleeding/alleviate pain, prophylaxis use, major surgery use, and medication cost. Best-worst case scaling was used to derive preferences. Relative importance (RI) of preferences was modeled using a multinomial logit function. **RESULTS:** Most respondents were male (96.1%) with a mean age of 20.7 years (SD = 18.8). Most patients were hemophilia type A (88.5%) and the majority (88.5%) considered their disease "serious." The three most important patient-identified features were: time required to stop bleeding (RI = 19.3), possibility that the level of inhibitor may rise (RI = 14.3), and risk of contracting a virus from the product (RI = 13.5). **CONCLUSION:** Inhibitor patients and caregivers have specific treatment preferences based on product features. Overall, patient preferences were similar to physicians (Lee, 2008), although patients placed more importance on the risk of viral transmission, whereas physicians placed more on the time

to alleviate pain. In contrast, other research (Mantovani, et al., 2005) suggests greater importance of perceived viral safety among both physicians and pharmacists relative to patients.

PSY42

EFFECTIVENESS OF ONCE-DAILY EXTENDED-RELEASE (ER) TRAMADOL IN ACHIEVING CLINICALLY MEANINGFUL IMPROVEMENT IN FUNCTIONING

Janagap C[1], Lee SP[2], Mody S[1], Ng DB[3], Schein JR[1]
[1]Ortho-McNeil Janssen Scientific Affairs, LLC, Raritan, NJ, USA, [2]Ortho-McNeil Janssen Scientific Affairs, LLC, Titusville, NJ, USA, [3]Ortho-McNeil Janssen Scientific Affairs, LLC, Chicago, IL, USA

OBJECTIVE: Assess the effects of tramadol ER once daily versus placebo in patients with moderate to moderately severe chronic pain due to osteoarthritis of the knee or hip. **METHODS:** Data for this post-hoc analysis were from a 12-week, randomized, double-blind, placebo-controlled, once-daily fixed dose-study of tramadol ER (100 mg–300 mg). Patients completed the WOMAC questionnaire at baseline and weeks 1, 2, 3, 6, 9 and 12. Items in each WOMAC subscale—pain (5-items), physical functioning (17-items) and stiffness (2-items) were combined and normalized from 0-to 100. The minimum clinically important difference (MCID) set at ten points improvement was determined from the literature. Mean subscale scores, percent mean change from baseline and the proportion of patients achieving a MCID at week 1 and 12 were assessed. **RESULTS:** A total of 809 patients were analyzed (604-tramadol ER; 205-placebo). Both cohorts had similar demographic and clinical characteristics at baseline. At week 1, mean change in WOMAC global and subscale scores from baseline for tramadol ER and placebo ranged from 12–16 and 7–10 points, respectively. Significantly higher proportion of tramadol ER treated patients achieved MCID versus placebo ($p < 0.05$) as early as week 1 except in the stiffness subscale. By week 12, mean change for each subscale and total WOMAC global score for tramadol ER treated patients were significantly greater versus placebo ($p < 0.01$), however, only higher doses (200–300 mg) of tramadol ER treated patients achieved MCID versus placebo ($p < 0.01$)On pain subscale, significantly higher proportion of patients treated with tramadol ER 100 mg achieved MCID versus placebo at week 1 and 12 ($p < 0.05$). **CONCLUSION:** This analysis showed that treatment with tramadol ER in patients with chronic pain extended to improvements in physical function and stiffness as demonstrated by achieving MCID in all WOMAC scores.

PSY43

DISCOVERING THE STRUCTURE OF THE POWER OF FOOD SCALE (PFS) IN OBESE PATIENTS

Cappelleri JC[1], Bushmakin AG[1], Gerber RA[2], Leidy NK[3], Sexton C[3], Karlsson J[4], Lowe MR[5]
[1]Pfizer Inc, Groton, CT, USA, [2]Pfizer Inc, New London, CT, USA, [3]United BioSource Corporation, Bethesda, MD, USA, [4]Sahlgrenska Academy at Göteborg University, Göteborg, Sweden, [5]Drexel University, Philadelphia, PA, USA

OBJECTIVE: To assess the psychometric properties of the Power of Food Scale (PFS) in diverse populations of obese and non-obese individuals. **METHODS:** Data were obtained from adults in a clinical trial for a weight management drug (n = 1739; mean body mass index [BMI] [SD] = 38.6 [6.7]) and a web-based survey (n = 1275; overweight and obese [BMI 27–76 kg/m2] and non-obese [BMI 18–27 kg/m2]). Exploratory and confirmatory factor analyses were employed to discover the structure of PFS using the clinical data. The model developed was then tested using data from the web-based survey. The relationship between PFS domains and BMI was also examined. Logistic regression was used in the web-based survey to evaluate the association between obese status and PFS scores. **RESULTS:** Psychometric assessment of data from the clinical study indicated that the scale was best represented by a 3-factor, 2nd-order model—three domains and a composite domain (average of the three domains)—which was confirmed within the web-based survey (Bentler's Comparative Fit Index: 0.92 and 0.91, respectively). Cronbach's alpha for both data sets were high, ranging from 0.81–0.94 (three domains and a composite domain score). The relationships between BMI and each domain were subtle and approximately linear. An increase of one point in a PFS domain score increased the odds of being obese by 1.6–2.4 times (depending on the domain; domain scores range from 1 to 5). **CONCLUSION:** The structure of PFS is represented by a 3 factor, 2nd-order model with three domains (Food Available, Food Present, and Food Tasted) and a composite of them. This structure has high internal consistency and reliability, relates to BMI, and distinguishes between obese and non-obese subjects. The data indicate that the PFS can be used to evaluate the effects of treatment on patient perception of the power of food in trials of obese patients.

PSY44

LINGUISTIC VALIDATION OF THE HAEMO-QOL AND HAEM-A-QOL FOR USE IN INTERNATIONAL STUDIES

Chevallet L[1], Weatherall JH[2], Von Mackensen S[3]
[1]Mapi Research Institute, Lyon, Rhone, France, [2]Novo Nordisk, Bagsværd, Denmark, [3]Institute of Medical Psychology, München, Germany

OBJECTIVE: Prior to use in an international study collecting data from haemophiliacs, the Haemo-QoL and Haem-A-QoL underwent linguistic validation in 17 languages. Whilst the original Haemo-QoL was developed in British English, the Haem-A-QoL had been developed in Italian. For the purposes of linguistic validation, an English version of the latter was used as a basis for the translations. Seven distinct versions exist: an adult form (Haem-A-QoL) and child self-report and parent proxy versions (Haemo-QoL) for 3 distinct age groups (4–7, 8–12, 13–16 years). A rigorous methodology was required to ensure conceptual equivalence and cultural relevance across different languages. **METHODS:** For languages where no translation existed, the process was conducted by a specialist in each target country using the following standardized methodology: 1) two forward translations by professional translators, native speakers of the target language and fluent in English; 2) comparison and reconciliation of the translations by the specialist in the target country; 3) backward translation by a native English speaker; 4) comparison of source and backward version; 5) review by the developer for a selection of languages; creation of the different forms of the instrument; and 6) review by a clinician. Existing translations were integrated into the process as appropriate. **RESULTS:** Besides the challenge of ensuring conceptual equivalence with the original and cultural appropriateness, the translation process revealed two additional difficulties. When translating an expression, appropriate terms had to be found for each age group whilst maintaining consistency across all versions of the same language. **CONCLUSION:** The language versions of Haemo-QoL and Haem-A-QoL were established according to a rigorous translation methodology aiming to ensure conceptual equivalence across different language versions to facilitate international comparison and pooling of data. The linguistic validation process as a whole supports the advantage of integrating international feedback on concepts and wording before a questionnaire is finalized.