that of physicians’ preferences for middle-aged patients across most benefit levels. Compared to adult patients, parents have greater risk tolerance for treating severe CD symptoms, and smaller risk tolerance for treating moderate CD symptoms. **CONCLUSION:** Respondents indicated they are willing to accept defined mortality risks in exchange for clinical efficacy and that acceptance is affected by the degree of benefit, the patient’s characteristics and the nature of the SAE. Understanding risk-benefit preferences can assist in identifying appropriate treatments and in informing welfare-enhancing regulatory decisions.

**PR4**

**BACK PAIN IN GERMANY: ARE THERE DIFFERENCES CONCERNING HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN PATIENTS TREATED ACCORDING TO GUIDELINES, GUIDELINE INDEPENDENT AND PATIENT SELF-TREATMENT?**

Breitscheidel L, Stridde E, Kreyenberg K, Benter U, Eichmann F

1Kendle GmbH, Munich, Germany, 2Pfizer Pharma GmbH, Karlsruhe, Germany

**OBJECTIVES:** Back pain has a considerable impact on HRQoL, even with new medications, treatments and guidelines the degree of suffering for patients is high. The objective was to compare HRQol for patients with back pain in Germany for three different treatment groups (guideline-, non-guideline- and self-treatment-group). **METHODS:** Patients were consecutively recruited by physicians in general practice (n = 54) in 2005. Patients were categorized into the three groups according to pre-specified algorithms. All groups completed the generic SF-36, and the disease specific FFbH-I, von Korff Index and PHQ-D questionnaires. In addition, a retrospective chart review was conducted. HRQoL data was compared between the groups. **RESULTS:** A total of 145 patients took part in this study (n = 29 guideline-group, 44 non-guideline-group, 72 with self-treatment). Patients in the self-treatment-group were younger than patients in guideline- or non-guideline-group (49.8 vs. 59.4 vs 57.4 years, p = 0.0021). The groups did not differ significantly in gender or other socio-demographic characteristics. The von Korff Index was lowest (i.e. poorer) in the self-treatment-group and highest in the guideline-group (p = 0.0077). Regarding SF-36, patients in the guideline-group had the lowest physical (30.2 ± 8.5) and mental (41.2 ± 13.5) component scores, only the differences regarding physical component were statistically significant between the groups (p < 0.0001), those regarding mental component were not (p = 0.2875). Regarding PHQ-D items, the groups did not differ in frequency of major depressive and other depressive symptoms. The guideline-group had significantly higher burden of somatoform symptoms compared to the other two groups (p = 0.0219). The self-treatment-group had the highest FFbH-R total score (67.7 ± 21.5) compared to other two groups (p = 0.0056). **CONCLUSION:** From the here collected data, it seems that patients who are treated according to guidelines have reached a higher degree of suffering (poorer HRQoL) compared to those patients with either treated without guidelines and/or treat themselves. Further research is warranted to confirm our findings.

**PODIUM SESSION II: CANCER**

**CN1**

**USING THE FACT-NEUROTOXICITY TO EVALUATE QUALITY OF LIFE IN CANCER PATIENTS FROM ACROSS THE GLOBE**

Eremenco S, Du H, Arnold B, Herzberg T, Cella D

Evanston Northwestern Healthcare, Evanston, IL, USA

**OBJECTIVES:** Translation of PRO measures is an essential component of research methodology in preparation for multinational clinical trials. The FACT-Neurotoxicity (FACT-Ntx) is used to evaluate the quality of life of cancer patients suffering from neurotoxicity, a side effect of certain treatments. This study set out to linguistically validate the FACT-Ntx for use in Denmark, India, Lithuania and South Africa. **METHODS:** The study sample consisted of 176 patients (96 males and 80 females), with varying cancer diagnoses and a mean age of 51 years, speaking 11 languages: Afrikaans (15), Danish (25), Gujarati (15), Hindi (15), Kannada (15), Lithuanian (15), Malayalam (15), Marathi (15), Punjabi (15), Tamil (15) and Telugu (16). The FACT-Ntx was translated according to standard FACIT methodology. Patients diagnosed with any stage cancer on any treatment and experiencing neurotoxicity completed the respective translated version and then participated in cognitive debriefing interviews. Statistical analyses (descriptive statistics, one-way ANOVA and reliability analyses) were performed on the quantitative data. Participant comments were analyzed qualitatively. **RESULTS:** The FACT-Ntx translations showed good reliability and linguistic validity. The internal consistency of all languages combined was 0.86, and all items correlated at an acceptable level. In general, the Ntx score differed across self-reported Performance Status Rating (PSR) groups (nonparametric Kruskal-Wallis test p < 0.0001). A nonparametric Generalized Linear Model (GLM) approach (with multiple comparison adjusted significance level 0.017) showed a difference between ‘PSR = 0’ and ‘PSR = 1’ (p = 0.0002) and a difference between ‘PSR = 0’ and ‘PSR = 2’ (p < 0.0001), both with ‘PSR = 0’ patients reporting less neurotoxicity. **CONCLUSION:** The FACT-Ntx has shown acceptable reliability and linguistic validity in 11 languages. The instrument has also shown adequate sensitivity in differentiating patients with no symptoms and normal activity from patients reporting some symptoms. We consider these translations acceptable for use in international research and clinical trials.

**CN2**

**DEVELOPMENT AND VALIDATION OF OPTIMALLY WEIGHTED MEASURES OF GLOBAL HEALTH-RELATED QUALITY OF LIFE (QOL) AND UTILITY BASED ON A CANCER-SPECIFIC QOL INSTRUMENT**

Grimison PS, Simes Rj, Stockler MR

NHMRC Clinical Trials Centre, University of Sydney, Camperdown, NSW, Australia

**OBJECTIVES:** To facilitate the comparison of net benefits of cancer treatments in clinical trials by developing and validating a system to convert data from a QoL instrument into precise and optimally weighted global QoL measures and utilities. **METHODS:** Two-hundred cancer patients completed the Utility-Based Questionnaire-Cancer (UBQ-C), a validated 34-item cancer-specific instrument which includes scales of health status, overall QoL, disabilities and distresses. Patients were interviewed to elicit time trade-off (TTO) utilities for their own health states. A global QoL measure was derived from a weighted combination of the UBQ-C scales based on linear regression of health status on the individual scales. An equation to convert global QoL into utility was derived. Validity was examined using baseline data from a RCT of advanced breast cancer chemotherapy (n = 290). **RESULTS:** The weighted global QoL measure was more precise than the single-item QoL scales. Median scores (IQR) were much lower for the weighted global QoL measure: 0.77 (0.65, 0.85) than for the direct TTO utility: 0.98 (0.85, 1.0). The best model to predict utility from weighted global QoL was a power transformation: TTO = 1-(1-global QoL)2.1. The measures discriminated between RCT subjects with good and poor performance status: mean (95% CI) derived utility scores for ECOG 0-1 = 0.91 (0.89, 0.92), ECOG 2-3 = 0.75 (0.68, 0.81),