PCN79

HEALTH STATE PREFERENCE STUDY MAPPING THE CHANGE OVER THE COURSE OF THE DISEASE PROCESS IN CHRONIC LYMPHOCYTIC LEUKAEMIA (CLL)

Ferguson J[1], Tolley K[2], Gilmour L[1], Priaulx J[2]
[1]Bayer plc, Newbury, UK, [2]Mapi Values, Macclesfield, UK

OBJECTIVES: CLL is a common form of leukaemia associated with symptoms of tiredness, night sweats, weight loss, anaemia and infection. The objective of this study was to measure the comparative utility of eight disease states describing two first line treatments (MabCampath, chorambucil) and the progression-free and progressive stages of CLL following first, second and final lines of therapy. **METHODS:** In order to obtain societal preferences, we conducted a utility study in the UK with 60 members of the general public using the Time Trade-Off (TTO) method. The interviews were conducted face-to-face by trained interviewers using a TTO scale with a 10 year duration period. A Visual Analogue Scale (VAS) (0 being death and 100 being full health) was also included. Information on the condition and health states were developed using literature, in-depth interviews and validation with specialist nurses and a specialist physician. **RESULTS:** The mean utility scores according to the TTO were: progression-free after first-line therapy; 0.777, progressive after first-line therapy; 0.540, progression-free after second-line therapy; 0.650, progressive after second-line therapy; 0.470, progression-free after final-line therapy; 0.428 and progressive after final-line therapy; 0.279. The mean utility on first-line treatment was 0.619 for MabCampath and 0.623 for chlorambucil. The VAS scores had similar values. **CONCLUSIONS:** In conclusion, there was gradual decline in the utility score after each subsequent line of therapy for patients in progression-free states and for patients in progressive states. Utility decreased when patients moved from progression-free to progressive states after each line of therapy. These values can be used in cost-utility analyses of treatment pathways associated with CLL.

PCN80

PATIENT REPORTED QUALITY OF LIFE IN CANCER PATIENTS ON OPIOID THERAPY IS INFLUENCED BY CONSTIPATION

Van der Linden MW[1], van den Haak P[1], Penning-van Beest FJA[1], Klok RM[2], Herings RMC[1]
[1]PHARMO Institute, Utrecht, The Netherlands, [2]Wyeth Pharmaceuticals bv, Hoofddorp, The Netherlands

OBJECTIVES: To compare patient reported quality of life in cancer patients on opioid therapy with and without constipation. **METHODS:** Patients with a diagnosis of cancer, receiving opioids from all public pharmacies in The Netherlands, were recruited by a pharmacy worker to complete a generic questionnaire about opioid use and constipation and the EuroQoL-5-Dimensions questionnaire (EQ-5D) about generic Quality of Life (QoL). Patients were classified as having constipation or not based on self-reported bothersome side effect of the opioid and use of laxatives. EQ-5D index scores were compared with Wilcoxon Two-group test. **RESULTS:** A total of 113 patients using opioids from 170 pharmacies returned the questionnaires. Seventy-five (66%) of the cancer patients were classified as having constipation. Patients with and without constipation were similar with respect to age (mean ± standard deviation 66.1 ± 9.8 and 63.8 ± 12.6, respectively), gender (44% and 50% males, respectively) and type of opioid (most frequently oxycodone, fentanyl and morphine preparations in both groups). Patients with constipation more often reported problems with Pain (95% versus 92%) and Anxious/depressed Mood (52% vs. 42%), but less often with Self care (52% vs. 58%) than patients without constipation. The median [25th–75th percentile] EQ-5D index score among patients with constipation was lower compared to those without constipation (0.39 [0.19–0.69] vs. 0.63 [0.30–0.78], p = 0.10). **CONCLUSIONS:** Constipation in cancer patients using opioids has a substantial impact on patient's quality of life. Alleviation of constipation symptoms might help improve patient reported quality of life.

PCN81

CROSS-CULTURAL ADAPTATION INTO SPANISH AND ITEM REDUCTION OF THE UCLA-PROSTATIC CANCER INDEX (UCLA-PCI): A SPECIFIC HEALTH RELATED QUALITY OF LIFE (HRQOL) QUESTIONNAIRE FOR PROSTATIC CANCER

Vera-Donoso C[1], Cuervo J[2], Valero E[3], Rebollo P[2]
[1]Hospital Universitario La Fe, Valencia, Spain, [2]BAP Health Outcomes Research, Oviedo, Asturias, Spain, [3]Astellas Pharma, Madrid, Spain

OBJECTIVES: To carry out a cross-cultural adaptation into Spanish of the UCLA-PCI questionnaire and to validate a reduced version. **METHODS:** Firstly, forward-backward translations of the UCLA-PCI were made by two native (English and Spanish) translators and integrated into a preliminary version by an expert panel (two urologists and one radiologist). Comprehension of items was analyzed by 15 prostatic cancer (PC) patients by using a 4 levels likert scale. As a result, an initial version (UCLA-PCI 1.0) was reached by consensus. Next, 50 PC patients who had received treatment (radiotherapy or prostatectomy) 3 years before answered both the UCLA-PCI 1.0 and the generic HRQoL questionnaire SF-12 Health Survey. Exploratory factorial analysis -FA-, item-total correlations and confirmatory FA (promax oblique rotation) were applied to reduce the UCLA-PCI 1.0 into a 4 items scale (UCLA-PCI-brief). Internal consistency (Cronbach's α), feasibility and convergent validity (Spearman correlation with SF-12 and non parametric test for 2 independent samples, according to TNM tumor stage) were assessed. **RESULTS:** Internal consistency was high in UCLA-PCI 1.0 (0.856) and acceptable in UCLA-PCI-brief (0.731). UCLA-PCI 1.0 FA showed the same constructs that the original (urinary, bowel and sexual symptoms—function and bother). UCLA-PCI-brief FA revealed 3 functional dimensions: urinary (2 items; 56.16 of variance explained), bowel (1 item, 21%), intestinal (1 item, 15.28%). Moreover, correlations between UCLA-PCI–brief and SF-12 Mental and Physical Summaries Components were respectively: urinary (0.31 and 0.38; $p > 0.05$), intestinal (0.29 and 0.634; $p < 0.05$) and sexual (0.04 and 0.33; $p > 0.05$). Finally, significant differences were found in the UCLA-PCI scores between patients with a more favorable PC stage and patients with a worse prognosis. **CONCLUSIONS:** The Spanish version of the UCLA-PCI maintains the same structure as the original. An item reduced version (UCLA-PCI-brief) with adequate properties has been developed.

PCN82

TESTING THE MEASUREMENT EQUIVALENCE OF PAPER AND INTERACTIVE VOICE RESPONSE (IVR) VERSIONS OF THE EQ-5D

Lundy JJ, Coons SJ
University of Arizona, Tucson, AZ, USA

OBJECTIVES: Electronic data capture technologies, such as interactive voice response (IVR) systems, are emerging as important alternatives for collecting patient-reported outcomes data. The objective of this study was to assess the measurement equivalence of an IVR version of the EQ-5D with the original paper version. **METHODS:** This study utilized a crossover design with subjects randomly assigned to one of two assessment orders: 1) paper then IVR or 2) IVR then paper. A convenience sample of in-treatment outpatient cancer clinic patients (n = 139) were

asked to complete each assessment two days apart. The analyses tested for mean differences (repeated measures ANOVA) and reliability (intraclass correlation coefficient [ICC]) to assess measurement stability over time. Equivalence of the means was established if the 95% confidence interval (CI) of the mean difference was within the minimally important difference (MID) interval: –0.035 to .035 for the index and –3 to 3 for the EQ VAS. Adequacy of the ICC was established by comparing the ICC 95% lower CI with a critical value of 0.70. **RESULTS:** The per protocol analysis included 109 subjects for the EQ VAS and 113 subjects for the index. For the EQ-5D index, the means (SD) of the paper and IVR administrations were 0.790 (0.172) and 0.800 (0.180), respectively. The 95% CI of the mean difference was –0.024 to 0.006, which was within the equivalence interval. The ICC was 0.894 (95% lower CI 0.857), significantly different from 0.70. For the EQ VAS, the means (SD) were 72.0 (19.7) for paper and 74.1 (19.8) for IVR. The 95% CI of the mean difference was –3.784 to –0.484, partially within the equivalence interval. The ICC was 0.897 (95% lower CI 0.859) also significantly different from 0.70. **CONCLUSIONS:** This analysis provides evidence that the EQ-5D scores on the IVR version were equivalent to those obtained on the original paper version.

PCN83

PERFORMANCE AND ADEQUACY OF PATIENT-PERSPECTIVE CRITERIA IN THE ASSESSMENT OF TEST-RETEST RELIABILITY: THE CASE OF THE PERFORM QUESTIONNAIRE

Baro E[1], Rodríguez C[2], Gascón P[3], García-Mata J[4], Colomer R[5], Cassinello J[6], Carulla J[7], Valentín V[8], Gasquet JA[9]

[1]3D Health Research, Barcelona, Spain, [2]Hospital Clínico Universitario de Salamanca, Salamanca, Spain, [3]Hospital Clínic i Provincial de Barcelona, Barcelona, Spain, [4]Hospital Santa Maria Nai, Orense, Spain, [5]Centro Oncológico MD Anderson, Madrid, Spain, [6]Hospital Universitario de Guadalajara, Guadalajara, Spain, [7]Hospital General Mateu Orfila, Menorca, Spain, [8]Hospital 12 de octubre, Madrid, Spain, [9]AMGEN S.A, Barcelona, Spain

OBJECTIVES: Cancer-related fatigue (crF) is a frequently reported complaint in cancer patients and survivors. The Perform Questionnaire (PQ) is a recently validated 12-item scale to assess perceptions and beliefs about crF throughout the dimensions 'Physical limitations', 'Activities of daily living', 'Beliefs and attitudes'. This study aims to explore the performance of different ways for identifying stable patients in the assessment of test-retest reliability. **METHODS:** Patients with a moderate level of crF participated in an observational and longitudinal multi-centre. PQ and a 100 mm horizontal visual analogue scale for fatigue intensity (VAS) were administered at inclusion and 3 months later. Stability concerning crF was defined as either: 1) absence of self-reported health change, using a standard self-administered health status item (HSI) at the second visit on a Likert-type ordinal scale with 13 response options, or 2) Fatigue VAS score change between visits <5 mm. Test-retest reliability (Intraclass correlation coefficient, ICC) was assessed for the PQ overall and for the three dimension scores, using each method 1 and 2. **RESULTS:** Baseline sample characteristics (n = 437) were: 60.5% women, mean age 59.1 years, an average of 2.21 years since diagnosis, 33.6% breast cancer, 54.7% with metastasis, Karnofsky mean score 80.9, and 29.1% with anaemia. ICC values obtained using the method 1 (n = 58) didn't reach the standard value recommended (0.70) for the overall (0.68) neither the dimension scores (0.52–0.68), while ICC values obtained using the method 2 (n = 64) were satisfactory and reached the standards accepted for this psychometric propertie assessment (0.83 for the overall score and ranging between 0.77 and 0.84 for the three dimension scores). **CONCLUSIONS:** Patient-perspective is a relevant approach in the assessment of the psychometric properties of the patient-oriented health outcomes measures. The performance and adequacy of different patient-perspective criteria can conduct to different conclusions concerning specific psychometric properties.

PCN84

THE PATIENT-REPORTED OUTCOMES MEASUREMENT INFORMATION SYSTEM CANCER PAIN ITEM BANK (PROMIS-CA PAIN)

Lai JS[1], Garcia S[1], Cella D[1], George J[2]

[1]ENH/NWU, Evanston, IL, USA, [2]Evanston Northwestern Healthcare, Evanston, IL, USA

OBJECTIVES: Among patients with cancer and other diseases, pain is a common experience that can negatively impact daily living. It is unclear whether pain experiences and their impact are diagnosis-specific or shared across conditions. We examined whether the United States general population-based PROMIS Pain Impact item bank can be used for measuring cancer pain, and the relationship between pain experience and pain impact. **METHODS:** PROMIS Pain Impact items included in field testing with oncology populations were selected through expert consensus. Multidisciplinary clinical input was obtained to ensure content coverage and the relevance of PROMIS pain items to cancer. Items' psychometric properties were reviewed when applicable. As a result, PROMIS-Ca Pain Impact consisted of 36 items across 3 areas: physical, emotion and social. The sample included 529 cancer patients (74% female, 82% White, mean age = 56). Analyses included item scalability (item-scale correlation >0.3), unidimensionality (exploratory and confirmatory factor analysis, and multidimensional scaling), and IRT model fit (S^2-G^2 & S^2-X^2). **RESULTS:** All 36 PROMIS-Ca Pain Impact items met preset analysis criteria to form a unidimensional item bank. Additional analyses showed that scores from Pain Impact were significantly correlated with Pain Quality items assessing pain intensity ($r = 0.56$), frequency ($r = 0.58$) and duration ($r = 0.64$), and could significantly differentiate patients with different degrees of neuropathic pain, $F(4527) = 37.4$, $p < 0.0001$, emotional distress as measured by two items $F(4472) = 122.53$, $p < 0.001$, and $F(4453) = 74.94$, $p < 0.001$. Similar results were found regardless of whether patients based their responses on their "worst" or "least" pain experience. **CONCLUSIONS:** PROMIS-Ca Pain is a psychometrically-sound and clinically meaningful measure for cancer patients. It is correlated with patients' pain experience. Our next step is to examine whether the same conclusion can be made with other disease groups. Ultimately, a statistical cross-walk of pain scores could be created to enable the comparison of pain scores between disease groups.

PCN85

PATIENT PREFERENCES IN THE THERAPY OF MULTIPLE MYELOMA

Mühlbacher AC[1], Berndt K[2], Lincke HJ[1], Nübling M[1]

[1]Gesellschaft für empirische Beratung mbH, D- 79211 Denzlingen, Germany, [2]Janssen-Cilag GmbH, Neuss, Germany

OBJECTIVES: Analyses of patients' preferences about their therapies are a prerequisite for shared decision making, but are still not widely performed. This study elaborates the importance of treatment aspects in the eyes of multiple myeloma (MM) patients using direct assessment and Discrete-Choice-Experiments (DCE). **METHODS:** After a literature review we conducted focus groups with 6–8 MM patients to collect the most important therapy aspects. Then, patients answered an online or paper-pencil questionnaire which asked for sociodemographic data, self-rated-health (SF12v2 variation) and patients' preferences about therapy. The latter were assessed using direct