Guidelines. Mode equivalence between paper and electronic versions of the EORTC Quality of Life Questionnaire (EORTC QLQ-C30;v3.0) and its Breast Cancer Module (QLQ-BR23;v1.0) was evaluated, as well as their usability on two electronic devices with different screen sizes. **METHODS:** Adult women with metastatic breast cancer (mBC) who had not received chemotherapy for metastatic disease were screened. Using an alternating crossover study design, half completed questionnaires on paper first, followed by a tablet (10.1″screen) and a handheld (4.5″screen); the other half used the handheld first, followed by tablet and paper. To optimize recall, the think-aloud method was used and cognitive debriefing interviews were conducted after each questionnaire was completed on each device. Usability questions were asked after completion of both questionnaires on a device. **RESULTS:** 10 mBC patients were interviewed. Most patients reported that their answers would not differ on paper vs devices (tablet:C30=70%;BR23=100%), (handheld:C30=90%;BR23=90%). No participants attributed potential differences to interpreting items differently on the different modalities. 100% easily accessed questionnaires on the devices, understood instructions and easily moved from question-to-question. 90% were satisfied with the touchscreens, and all noted they could use either device independently. Patients preferred the tablet vs handheld due to its larger screen; yet all preferred the handheld's one-question-per-screen presentation, which allowed for greater focus. All patients indicated that screen size did not influence usability and that either device was acceptable to complete questionnaires. **CONCLUSIONS:** This study demonstrated mode equivalence between paper and electronic versions of EORTC-C30 and BR23, as well as between two devices. The devices were equally acceptable, providing evidence for their usability to collect PRO information from similar patients in clinical trials.

PCN208

PREVALENCE AND REASONS FOR NONADHERENCE TO AROMATASE INHIBITORS IN AN OUTPATIENT ONCOLOGY CLINIC

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OBJECTIVES: Nonadherence to hormonal therapy is known to impact health outcomes in patients with breast cancer. We measured nonadherence to aromatase inhibitors using a novel, clinic-based patient-reporting system. **METHODS:** Patients of The West Cancer Center (Memphis, TN) were surveyed in the clinic prior to a scheduled appointment using the Patient Care Monitor system, a tablet-based, patient-reported outcomes platform. Adults diagnosed with breast cancer and prescribed an aromatase inhibitor were eligible to participate. The survey included 30 questions and used three established instruments, including the Morisky Medication Adherence Scale and Medication Adherence Reasons Scale. The survey polled patients on their adherence to aromatase inhibitors, reasons for nonadherence, and health literacy. **RESULTS:** Over the course of 45 days, 3016 patients were self-screened for eligibility and interest; 1105 indicated interest; and 110 patients were fully eligible and completed the survey. Respondents were well-distributed by medication: anastrazole (42.2%), exemestane (33.9%), and letrozole (23.9%). Most patients (82.6%) reported being fully adherent (missed 0 days) in the past week; however, only 67.9% reported high adherence (score = 4) according to the Morisky Medication Adherence Scale (Spearman rho= -0.457, p-value<0.0001). Mean adherence values or days missed did not differ significantly by medication or health literacy level. Among patients who reported missing at least one day in the previous week, the most often cited reasons were: simply missing the dose (44.4%), having problems forgetting things (38.9%), and concerns about side effects (33.3%). **CONCLUSIONS:** Adherence to hormonal therapy remains suboptimal and determining reasons for nonadherence prior to scheduled visits may assist providers in guiding patients. Moreover, the clinic's Patient Care Monitor system is a novel patient engagement platform to collect patient-reported adherence data outside of the medical encounter, and may be leveraged to provide adherence and toxicity information to the healthcare team in real time.

PCN209

INFLUENCE OF THE METHOD OF ANALYSIS ON ESTIMATES OF QALY TREATMENT DIFFERENCE: PHASE III TRIAL OF VINFLUNINE VERSUS BEST SUPPORTIVE CARE IN PATIENTS WITH TCCU

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OBJECTIVES: Utility analyses have previously been conducted for the Phase III trial of vinflunine (VFL) versus best supportive care (BSC) for the treatment of advanced or metastatic transitional cell carcinoma of the urothelial tract (TCCU). Results were presented according to progression status. The present study aims to calculate quality-adjusted life years (QALYs) for each patient and summarise results by treatment group. **METHODS:** QALYs were calculated by patient using the area under the curve technique. Assumptions included that changes between utility measures over time were linear and utility at the time of death is zero. Once QALYs were calculated for all patients, univariate summaries were produced for both treatments separately considering different scenarios based on when baseline was recorded and how censored patients are handled in the QALY calculation. The mean differences between treatments were evaluated using p-value derived from a two sample t-test and non-parametric Wilcoxon rank sum test. An analysis of covariance (ANCOVA), adjusting for baseline utility, was also performed. **RESULTS:** A total of 242 patients from the VFL and 103 from the BSC group had utility data and were eligible for the study. All BSC patients were observed to die, whilst 6% of VFL patients were censored and required imputation of death for QALY calculation. The estimated mean difference in QALY between treatment groups always favoured vinflunine regardless of method of analysis. Point estimate ranged between -0.152 to -0.061. ANCOVA analyses move the point estimate slightly more in favour of vinflunine compared with unadjusted analyses. This was expected as the baseline utility was higher in the BSC group (0.781) compared to vinflunine (0.766). **CONCLUSIONS:** Sensitivity analyses show that difference mean estimates in QALYs in favour of vinflumine can be quite different depending on how censored patients are handled especially when proportion of censoring differs by treatment group.

PCN210

LONG-TERM EQ-5D SCORE FOR PATIENTS WITH METASTATIC BREAST CANCER; COMPARISON OF FIRST-LINE ORAL S-1 AND TAXANE THERAPIES IN THE RANDOMIZED "SELECT" TRIAL

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OBJECTIVES: The present study used long-term EQ-5D scores to evaluate patients with metastatic breast cancer (MBC) in a randomized control trial (RCT). **METHODS:** Patients with HER2-negative MBC were randomly allocated to the S-1 (an oral fluoropyrimidine) or taxane (paclitaxel or docetaxel) group. The primary endpoint was overall survival (OS), and QOL was a secondary endpoint. EQ-5D scores were surveyed at pre-treatment, three months after randomization, and every six months thereafter. Mean scores were assessed by repeated measured ANOVA including baseline, group, time and interaction of group and time. Minimal important difference (MID) analysis was also performed by defining the MID of EQ-5D as 0.05 or 0.1. When MID analysis was applied to the score during fist-line therapy, progression was treated as a competing risk. **RESULTS:** A total of 618 patients with MBC were randomly allocated to both groups (N=309 each). S-1 was non-inferior to taxanes for OS (median OS: S-1, 35.0 months; taxanes, 37.2 months). The number of patients in the EQ-5D population was 208 and 175 in S-1 and taxane groups, respectively. Mean duration of the EQ-5D response was 21 months for both groups. Mean EQ-5D scores up to 60 months were 0.748 and 0.741 in S1 and taxane groups, respectively. No significant difference was observed by ANOVA or MID analysis. During first-line therapy, mean EQ-5D score was 0.810 and 0.781 in S-1 and taxane groups up to 36 months, although in the post-progression period, scores decreased to 0.729 and 0.703, respectively. Gray's test revealed that S-1 significantly delayed the decrease in QOL score. The size of the MID (0.05 or 0.1) did not influence the results. **CONCLUSIONS:** This study analyzed long-term EQ-5D scores of patients with MBC from RCT data. The QOL score of S-1 was higher during first-line therapy.

PCN211

SENSITIVITY ANALYSIS IN DISCRETE CHOICE EXPERIMENTS FOR RARE DISEASES – AN ANALYSIS WITHIN THE PIANO-STUDY

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OBJECTIVES: Discrete choice experiments (DCE) are an important method for capturing data on the patient preferences. Neuroendocrine tumors (NET) are a rare disease and therefore a sufficient number of study participants for preference studies is difficult to recruit. Moreover there is hardly any international standard for the determination of the appropriate number of study participants in DCEs. Amongst others, suggestions on sample size have been made by Orme and Louviere. **METHODS:** Patient-relevant outcomes concerning alternative treatment options of NET were weighted using a DCE including six attributes. Akaike information criterion (AIC), and Bayesian information criterion (BIC) together with the standard error (SE) were used to check the model fit and to determine the most appropriate sample size. For the sensitivity analysis different participants were randomly drawn from the study sample. **RESULTS:** N=275 NET-patients (48.5% male, mean age 58.4 years) could be included. With the maximum number of included participants all six attributes resulted in significant values (p<0.05). This sample sizes then accounts for an AIC=3901.391, BIC=4043.999 and a mean standard error (SE) of 0.057. Within the analysis an increasing sample size linearly improves the model fit. When including N=30 the mean SE does not fit the given 0.05 level (0.173). This improves with a higher sample size. Consequently, including N=90 results in a mean SE below 0.1 with BIC=4043.999 and AIC=3901.391. The mean SE falls to 0.065 when including N=210 (BIC=3169.285; AIC=3032.256) **CONCLUSIONS:** Using the sensitivity analysis it can be shown that the model fit improves proportionally. An optimal sample size could therefore be approximated. Based on the preliminary results it is evident that with the given design and the given number of attributes and level a total N of at least 275 participants is appropriate to conduct a DCE.

PCN212

PATIENT PREFERENCES CONCERNING ALTERNATIVE NET TREATMENT OPTIONS – THE PIANO-STUDY

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OBJECTIVES: Neuroendocrine tumors (NET) are relatively rare, usually slow-growing malignant tumors. So far there are no data on the patient preferences regarding the therapy of NET. This empirical study aimed at the elicitation of patient preferences in the drug treatment of NET. **METHODS:** Based on qualitative patient interviews and an AHP, patient-relevant outcomes were analyzed and weighted using a discrete choice experiment (DCE). Six patient-relevant attributes were included. Patients were recruited with the help of a NET support group. For the DCE an experimental design (3*3 + 3*6 Design) was created using Ngene. The selected design consisted of 84 choices, which were divided into 7 blocks. Participants were randomly assigned to these blocks. The analysis of DCE included random parameter logit models, conditional logit models, and latent class models. **RESULTS:** N = 275 NET-patients (51.6% female, mean age 58.4 years) participated. Under the chosen decision model the preference analysis within the random parameter logit model, taking into account

the 95% confidence interval, showed a predominance for the attribute "overall survival" (coef: 1,568). The attributes "response to treatment" (coef: 0,617) and "stabilization of tumor growth" (coef: 0,547) followed. However, the side effects "nausea/vomiting" and "diarrhea" are considered of relatively equal importance (coef: 0,544 / 0,413). The analysis of possible subgroup differences using latent class analysis revealed three preference patterns. The adverse event "occurrence of abdominal pain" had a significant effect in just one class. **CONCLUSIONS:** The results thus provide evidence about how much influence a treatment capacity has on therapeutic decision. The preference measurement showed that "overall survival" has the strongest influence on the therapeutic decision. The preference analysis also made it clear that the participants weight the outcome attributes higher than the side effects. Thus it becomes clear that a mono-criterial decision would not fully reflect the patient benefits.

PCN213

IMPACT OF STAGING AND HORMONE SENSITIVITY ON QUALITY OF LIFE IN US PROSTATE CANCER PATIENTS

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OBJECTIVES: To evaluate the difference in quality of life of hormone-sensitive (HSPC) and castrate-resistant (CRPC) prostate cancer patients in the US as measure by EuroQol-5D and FACT-P. **METHODS:** Data were extracted from the Adelphi Real World Prostate Cancer Disease-Specific Programme© (DSP), a cross-sectional survey of 137 urologists and oncologists and their prostate cancer patients, conducted in the US between February and May 2014. Physicians completed detailed record forms for the next 12 consulting patients receiving prescribed drug therapy for prostate cancer. Each patient was invited to complete a questionnaire which included the EQ-5D and FACT-P tools. The scores were compared between HSPC and CRPC patients using t-tests or Mann-Whitney tests. **RESULTS:** The physicians provided records for 1,330 prostate cancer patients of which 604 were categorized as HSPC and 492 as CRPC. Among the HSPC patients, 203 completed the EQ-5D, the mean utility index score was 0.84, which was significantly better (p=0.0004) when compared to 0.78 (n=182) for CRPC patients. Similarly, the quality of life as measured by FACT-P was generally better among HSPC patients than CRPC patients in a number of domains, including physical well-being [21.0 (n=203) vs 19.6 (n=187), p=0.0119] and emotional well-being [15.8 (n=203) vs 14.7 (n=186), p=0.0217], but not the social well-being [18.6 (n=206) vs 19.7 (n=187), p=0.0382] and there was no statistical difference in the FACT-P score [102.1 (n=198) vs 98.9 (n=182). In HSPC patients, worse QoL was seen with patients with a worse ECOG performance status. **CONCLUSIONS:** The development and subsequent progression of prostate cancer to CRPC represents a significant additional humanistic burden for patients, as indicated by the significant HSPC vs CRPC difference captured by EQ5D. Multiple domains particularly physical and emotional may contribute to the deterioration of quality of life during disease progression.

PCN214

ESTIMATING EORTC-8D HEALTH STATE UTILITY VALUES FROM EORTC QLQ-C30 SCORES IN RELAPSED MULTIPLE MYELOMA

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OBJECTIVES: To derive EORTC-8D health state utility values from patient-reported EORTC QLQ-C30 scores from the ASPIRE trial. ASPIRE is a randomized, open-label, phase 3 trial, which evaluated the efficacy and safety of carfilzomib with lenalidomide and dexamethasone (KRd) versus lenalidomide and dexamethasone (Rd) in relapsed multiple myeloma. **METHODS:** EORTC-8D is a condition-specific preference based measure with eight dimensions from EORTC QLQ-C30: Physical functioning, role functioning, pain, emotional functioning, social functioning, fatigue and sleep disturbance, nausea and constipation and diarrhea. Episodic random utility model (ERUM) was used to derive the EORTC-8D health state utility values from EORTC QLQ-C30 at baseline for the overall ASPIRE trial population and trial arms using the UK tariff. **RESULTS:** Estimated EORTC-8D utility values ranged from 0.291 to 1.0 which is congruent with the expected range of health utility values based on a UK tariff. The estimated baseline (cycle 1) utility values [mean (SD)] were 0.7834 (0.1289) for the overall population (n=734), 0.7851(0.1266) and 0.7816 (0.1314) for the KRd (n=370) and Rd (n=364) treatment arms, respectively. **CONCLUSIONS:** The EORTC-8D enables QALYs to be directly estimated using the EORTC QLQ-C30 as an alternative to generic measures which may not be as sensitive to quality of life changes in cancer. This measure will provide appropriate and useful information for cost per QALY analysis.

PCN215

MAPPING HEALTH STATE UTILITY VALUES FROM EORTC DATA COLLECTED FROM A CLINICAL TRIAL POPULATION WITH RELAPSED/REFRACTORY MULTIPLE MYELOMA

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OBJECTIVES: Health state utility values (HSUVs) are required for cost-effectiveness analysis of new medicines. Health-related quality-of-life data collected from the widely accepted EQ-5D are often not available and data from other instruments need to be mapped using algorithms. The objective of this study was to map HSUVs using data from a clinical trial of patients with relapsed/refractory multiple myeloma (RRMM). **METHODS:** Patient-level EORTC QLQ-C30 and EORTC QLQ-MY20 data were collected in a clinical trial of RRMM patients (n=640) and mapped to EQ-5D scores using published algorithms. Descriptive summaries of mapped EQ-5D scores were estimated overall, and treatment regimen by: health state (pre-progression, progressive disease), response (with/without complete response), and adverse events (with/without grade ≥3 AEs). Generalized estimating equation (GEE) models provided direct estimation of HSUVs, controlling for confounders. Mapped HSUVs were compared with published HSUVs in RRMM to assess reliability. **RESULTS:** The algorithm that included the EORTC QLQ-C30 and EORTC QLQ-MY20 produced reliable HSUV estimates providing greater differentiation between health states. The overall mean estimate for progression-free disease (PFD) was 0.733. PFD with response was 0.744 and PFD with no response was 0.704. The difference between scores with/without grade 3 AEs suggested a utility loss of 0.029; the AE decrement was greater (0.034) when using a proxy measure of patients who were off treatment but not in progressive disease. Similar patterns across the health states were seen by treatment regimen throughout the duration of the trial. GEE results were consistent with descriptive summaries. **CONCLUSIONS:** Mapped EQ-5D scores showed a consistent trend across health states, with higher HSUVs for pre-progression than progressive disease, for response versus no response, and without AEs versus with AEs. HSUVs were dependent on disease state and treatment regimen. The algorithm including both the EORTC QLQ-C30 and EORTC QLQ-MY20 provided reliable HSUV estimates in this RRMM population.

PCN216

ALTERNATIVE REGRESSION METHODS FOR MAPPING UTILITIES IN ONCOLOGY

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OBJECTIVES: Mapping a disease specific measure of quality of life to a generic instrument is one available technique to obtain utility values for cost-effectiveness studies. Based on a literature review on mapping techniques in oncology, we found that three models performed best: an OLS (Ordinary Least Square) regression with spline transformation, a multinomial logistic regression and a beta binomial regression. Our objective was to compare those three methods and a standard OLS regression for the mapping of the EORTC QLQ-C30 questionnaire to EQ-5D in patients with non-small cell lung cancer (NSCLC). **METHODS:** We used data from a cross-sectional study performed in a Canadian cancer centre where QLQ-C30 and EQ-5D questionnaires were completed on a single visit by 172 patients. We compared the results obtained with the OLS regression and the other methods according to the goodness-of-fit of the model (adjusted-R2) and the predictive ability (Mean Absolute Deviation or MAE and the Root Mean Square Error or RMSE). Analyses were replicated for 3 utility tariffs (US, UK and France). **RESULTS:** We found a mean observed utility of 0.6768 in our sample (standard deviation = 0.2848). The OLS regression with spline dominated all other methods, whichever tariff was used. With the UK tariff, the adjusted R2, MAE and RMSE were 0.6507, 0.1120 and 0.1683 respectively for the OLS with spline, vs. 0.5796, 0.1301 and 0.1847 respectively for the standard OLS. Better goodness-of-fit and predictive ability were obtained with the US tariff (adjusted R2 of 0.6900, MAE of 0.0694 and RMSE of 0.1114 for OLS with splne). **CONCLUSIONS:** Using OLS with spline provides a notable improvement in goodness-of-fit and a better predictive ability compared to other regressions. Further analysis will be performed to observe the robustness of those results on other datasets.

PCN217

HRQOL AND HEALTH UTILITY IMPACT ON PATIENTS WITH NEWLY DIAGNOSED MULTIPLE MYELOMA IN US AND EUROPE: A SYSTEMATIC LITERATURE REVIEW

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OBJECTIVES: This systematic literature review (SLR) aimed to identify health related quality of life (HRQoL) and health utility parameters among newly diagnosed multiple myeloma (MM) patients. **METHODS:** Systematic searches were conducted in literature databases including Embase® and MEDLINE® from Januray 2005 to June 2015. English language studies, regardless of design and intervention were included. Each study was reviewed by two independent reviewers; any disagreements were resolved by a third reviewer. **RESULTS:** Out of the 680 citations retrieved from literature databases, 12 were included in the review. The included studies were observational (n=6), randomised controlled trials (n=5), or cost-effectiveness analysis (n=1). Of 12 included studies, seven were conducted in US, three in Europe, and one each in Europe/US and Europe/other countries. Most commonly reported HRQoL scales were EORTC OLQ-C30, QLQ-MY20, and FACT-MM; while, health utility was estimted by EQ-5D. The HRQoL was significantly impaired in patients with MM compared to normative patients in terms of EORTC QLQ-C30 ($p<0.01$); with QoL, dyspnoea, physical functioning, role functioning, and social functoning subscales being the most affected. Further, disease progression was associated with a worsening in HRQOL scores ($p<0.001$). Impaired HRQoL was reported in patients with MM because of disease related symptoms like bone pain and fatigue. Mean pain scores worsened with more severe disease stage ($p<0.05$). Impaired HRQoL due to higher fatigue and pain scores was associated with shorter overall survival. Males had better HRQoL scores compared to females (p=0.04) and blacks had better HRQoL scores compared to non-blacks (p=0.03). Additionally, impaired health-related utility values were reported in patients with MM as sugested by a mean EQ-5D score of less than 0.5. **CONCLUSIONS:** Disease severity, gender, and race are few of the parameters that are associated with deterioration of HRQoL in patients with newly-diagnosed MM. Delaying disease progression could possibly help to improve HRQoL.

PCN218

FIELD MONITORING OF THE Z BENEFITS FOR BREAST CANCER OF THE PHILIPPINE HEALTH INSURANCE CORPORATION

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