### 13th Euro Abstracts

#### A275

**METHODS:** A total of 80 patients from Severance Hospital were consecutively included in a pilot study. Logistic regression analysis and ROC analyses identified the most predictive items from a set of questionnaires (EORTC-QLQ-C30, HADS, and Hornheide Screening Instrument) and other additional questions. The development of the CAT screening tool comprises generating an item bank, developing the CAT-algorithm and applying and implementing the CAT in clinical practice. **RESULTS:** Data from 103 breast cancer patients (mean age 58.8, SD 12.0) were analyzed. The EORTC QLQ-C30 scales Emotional Functioning and Role Functioning as well as the yes–no question after psychiatric/psychological/pyschotherapeutic treatment at any point in lifetime showed high predictive power with regard to need for POT (AUC = 0.88; CI 95% 0.82–0.95). The generation of the item bank resulted in 52 preliminary items which will be subjected to further analyses. **CONCLUSIONS:** The implementation of precision measures for POT is essential for providing comprehensive and high-quality cancer care. CAT methodology contributes to the reduction of patient burden and assessment duration, and increases efficiency as well as measurement precision.

#### PCN124

**OBJECTIVES:** Diagnosis and treatment of cancer entail a considerable amount of distress which in a large percentage of patients would require psychosocial treatment (POT). There is though a lack of precise and economic measures for assessing the need for POT. Its detection in clinical routine often depends on procedural and personnel conditions. The aim of the study was the development and implementation of a patient-reported outcome tool for the screening of distress, a further aim is the construction of a computer-adaptive testing (CAT) version.

**RESULTS:** Literature research resulted in 588 fatigue items, from which 44 were selected after comprehensive expert reviews. Based on feedback from 52 oncological and 18% of the time for colorectal cancer. This compares with an overall publication frequency for phase II trials conducted in Asia or Europe. However, trial sponsorship did not impact publication frequency. **CONCLUSIONS:** PROs were most frequently included in phase II trials conducted in Asia or Europe. However, trial sponsorship did not impact publication frequency. **CONCLUSIONS:** PROs were most frequently included in phase II trials conducted in Asia or Europe.

#### PCN126

**OBJECTIVES:** To compare the economic and patient-reported outcomes between outpatient home-based and inpatient hospital-based chemotherapy in advanced colorectal cancer patients. **METHODS:** A total of 80 patients from Severance Hospital in Seoul, Korea, who had stage III colorectal cancer and underwent home-based (n = 40) or hospital-based chemotherapy (n = 40) with a FOLFOLX regimen between January 2007 and April 2008 were enrolled. Patient satisfaction data were collected by a self-administered questionnaire survey. Based on hospital charge records, average cost (in 2008 Korean won) per chemotherapy session was estimated and compared between home- and hospital-based chemotherapy from a societal perspective. **RESULTS:** Patients receiving chemotherapy at home showed higher satisfaction with their treatment (mean satisfaction score: 3.58 ± 0.15, 5-point Likert-type scale, with a high satisfaction score indicating higher satisfaction) than those undergoing hospital-based chemotherapy (β = 0.271, P = 0.001). Additionally, home-based therapy reduced the cost per chemotherapy session by 16.6%, compared with hospital-based treatment (1,694,216 vs. 2,030,383 Korean won [Kw], 1200 Kw = 1 US dollar). The largest cost reduction was attributable to medical costs (~201,122 Kw), followed by caregiver’s opportunity costs (~135,000 Kw). **CONCLUSIONS:** Higher satisfaction and lower economic cost for home-based chemotherapy suggests that home-based chemotherapy could be a popular and cost-effective treatment option for colorectal cancer patients who are eligible for home-based chemotherapy.

#### PCN127

**OBJECTIVES:** To compare the economic and patient-reported outcomes between outpatient home-based and inpatient hospital-based chemotherapy in advanced colorectal cancer patients. **METHODS:** A total of 80 patients from Severance Hospital...
functioning MCID estimates for improvement and deterioration were (11, 2*) and those for communication deficit were (9, 7*). The estimates with asterisks were less than the 0.2 SD threshold and were therefore excluded from our MCID ranges. Our MCID estimates therefore range from 3 to 14. CONCLUSIONS: These estimates can help to provide clinicians with the clinical relevance of changes in HRQOL over time and in conjunction with other measures of efficacy, help to assess the value of a health-care intervention. The findings also indicate that more sensitive measures may be needed to detect certain changes. Furthermore, the estimates can be useful in determining sample sizes in the design of future clinical trials.

**PCN/12**

**EFFECTS AND MEDICAL COSTS OF A STRUCTURED PSYCHOLOGICAL GROUP INTERVENTION FOR BREAST CANCER PATIENTS AFTER SURGERY**

Shimomura K1, Shiroyo T1, Sagara Y1, Tobata R1, Ueno H1, Kubota Y1, Mori T1, Amano K1, Terada S1, Mori M1, Yajima T1, Kurasaki H1, Sato S2, Hosaka T2

*Ronse University, Kanata, Shiga, Japan; 2Osaka Medical Center for Adults, Higashi, Shiga, Japan; 3Kanazawa University, Kanazawa, Japan; 4Tokyo, Japan; 5Oita University, Tokyo, Japan;* 6Okayama University, Okayama, Japan; 7Tokai University, Tokyo, Japan

OBJECTIVES: To clarify the details of psychosocial health status, the effects and related costs of psychosocial group intervention in post-breast cancer surgery patients. METHODS: Structured psychosocial group intervention (90 min/week × 5 sessions) was conducted for 66 patients aged 20–79 years who were receiving breast cancer treatment at three hospitals in Japan (intervention group). The intervention was conducted 2 months to 3 months after radical surgery. HRQOL and psychosocial function were investigated prospectively for outcome. The survey included 1) EORTC QLQ-C30 for HRQOL; and 2) POMS, MAC scale, and a characteristic self-efficacy scale for psychosocial function. It was conducted at registration, week 4 (group therapy conclusion), and month 6. Prior to the intervention study, a group that fulfilled the same eligibility criteria but did not receive psychosocial group intervention was studied (n = 116; nonintervention group). The same outcomes were measured and compared using multivariate analysis adjusted for disease stage, chemotherapy, and hospital. Direct medical costs were obtained from receipt data, and information on travel expenses, direct nonmedical costs, and indirect costs (productivity costs) were collected simultaneously with the HRQOL survey. RESULTS: In HRQOL and psychosocial function, an intervention effect was seen in fatalism (MAC-F). In only a subgroup analysis by hospital, effective cognitive function was seen in HRQOL (EORTC-CF), tension-anxiety (POMS-TA), helplessness/hopelessness (MAC-H), and fatalism (MAC-F). However, these effects were not seen at 6 months. Total medical costs including indirect costs during the 6 months were ¥840,000 for the intervention group and ¥750,000 for the nonintervention group. CONCLUSIONS: Structured psychosocial group intervention for post-breast cancer surgery patients had a uniform effect in improving HRQOL and psychosocial function. It is significant that a benefit was obtained in the early postoperative period when HRQOL is most easily damaged. Medical costs did not differ significantly between the groups.

**PCN/129**

**A DATABASE REVIEW OF PATIENT-REPORTED OUTCOME STUDIES IN EORTC CANCER CLINICAL TRIALS**

Bottomley A1, Quinten C1, Mauer M1, Taphoorn M2, Flechtner HH3, Koller M4, Bottomley A1, Quinten C1, Mauer M1, Taphoorn M2, Flechtner HH3, Koller M4, Bottomley A1, Quinten C1, Mauer M1, Taphoorn M2, Flechtner HH3, Koller M4

*European Organisation for Research and Treatment of Cancer, Brussels, Belgium; 2Medisch Centrum Haaglanden—Weestseinde, Den Haag, The Netherlands; 3Otto-von-Guericke University Magdeburg, Magdeburg, Germany; 4University Hospital Regensburg, Regensburg, Germany*

OBJECTIVES: For the last two decades, QL has been increasingly assessed in the HRQOL measurement of cancer patients. Although QL is now a major component of cancer treatment evaluation, suffers from the absence of standards to assess QL and to interpret the clinical relevance of changes in QL. This review was conducted over a period of 13 years and therefore represents the first review to systematically present the HRQOL outcomes of cancer clinical trials. METHODS: EORTC QLQ-C30 was the instrument of choice in 85% of trials. In the last decade, 15 QL tools were used in 13% of trials. In 60% of trials, QL was included as an outcome in the studies investigating therapies in cervical carcinoma but not in only one study. Prognostic value of QoL was assessed in only two trials (15%). A statistically significant difference in QOL between treatment groups was studied in 69% studies, but the clinically meaningful difference was examined in only one study. Predictive value of QoL was assessed in only two trials (15%). Most widely observed methodological issues included lack of priori hypothesis (92%) and lack of methods to deal with missing data (85%). Other issues included lack of details on domain, variability in time points of assessment of a trial, and patient’s noncompliance, reported in ~60% studies. CONCLUSIONS: QOL is included as an outcome in the studies investigating treatments in cervical carcinoma but clinically meaningful interpretations of HRQOL results are rarely considered. The methodological shortcomings in the assessment and analysis of HRQOL outcomes should be examined further to derive clinically meaningful and correlating evidence.

**PCN/130**

**QUALITY OF LIFE, OUTCOMES, AND COSTS IN THE BELGIAN POPULATION RECEIVING 90Y-ZEVALIN FOR NON-HODGKIN LYMPHOMA: A STUDY FOR REIMBURSEMENT REVISION**

Krammer P1, Moenssens K2,3,4,5,6

*IPS Health Consulting, Brussels, Belgium*

OBJECTIVES: To compare hematologic toxicity, costs, health-related quality of life (HR-QOL), and outcomes observed in real life in the Belgian non-Hodgkin lymphoma (NHL) population receiving 90Y-Zevalin, with model-predicted data at reimbursement approval conducted on the basis of a clinical trial in heavily pretreated NHL. METHODS: Twelve of the 13 centers trained for 90Y-Zevalin administration at the time of reimbursement approval participated. All consecutive patients receiving 90Y-Zevalin for Rituximab-refractory NHL were included in this 1-year, multicenter, prospective, observational study. QOL assessments, based on a generic (EQ-5D) and a disease-specific (FACT-LYM) questionnaire, were performed at baseline (day of first administration Rituximab), day 8, month 1, 2, and 3 after baseline. Costing (€, 2008) was based on official tariffs and observed resource use. RESULTS: Over the 2-year recruitment period, 30 patients were included. Only one patient received hematopoietic growth factor prophylaxis. Hematological toxicity occurred in 79% of patients, but was generally mild. Grade IV neutropenia was reported in 16% of patients (35% predicted), grade IV thrombocytopenia in 23% (9% predicted), and grade IV anemia was not reported (4% predicted). EQ-5D as well as FACT-LYM assessments suggested no significant changes in HR-QOL over the study period and no impact of hematological toxicity on HR-QOL. The average total cost from the health-care payer perspective, covering costs of drugs, drug administration setting, and prophylaxis, amounted to €16,886 (Standard error 79 €). Hematological toxicity added €1,191 (Standard error: €582), constituting 7% of total costs (18,076 €). Observed costs were within 2% from predicted costs. Median time to progression (TTP) was 11.7 months (6.8 months predicted). CONCLUSIONS: This observational study confirmed the predicted tolerability profile, costs and outcomes associated with 90Y-Zevalin in a real-life patient population. Furthermore, the patient numbers treated with 90Y-Zevalin in real life were lower than anticipated (maximum 100 predicted).

**PCN/131**

**HEALTH-RELATED QUALITY OF LIFE (HRQOL) IN CERVICAL CANCER: CLINICAL SIGNIFICANCE AND METHODOLOGICAL ISSUES**

Siddappa T1, Gupta J1, Selgal M1

*Healthcare Private Ltd, Chandigarh, India*

OBJECTIVES: To assess the clinical utility of HRQOL instruments in RCTs in cervical cancer and evaluate pertinent methodological issues. METHODS: RCTs investigating HRQOL benefit of therapies in cervical carcinoma were included. The searches were conducted from inception to 2010. The citations were included in English language were included. Cochrane Central Register of Controlled Trials, MEDLINE and EMBASE were searched from inception to 2010. Two reviewers independently assessed the trials for inclusion and performed extraction. RESULTS: Of the 96 RCTs identified, 13 RCTs met the inclusion criteria. Ten trials compared different chemotherapeutic regimens in first- to third-line treatment. The most commonly used QoL instrument was Functional Assessment of Cancer Therapy (FACT-G) (46% trials). Alternatively, cancer-specific European Organization for Research and Treatment of Cancer–Quality of Life Questionnaire-C30 (EORTC QLQ-C30), SF-36, and Linear Analogue Scale Assessment (LASA 100 mm) were used in 8 trials. Done collectively in conjunction with the Brief pain Inventory (BPI). Only one trial reported HRQOL as a primary objective. HRQol results were presented adequately in 61% trials which were analyzable. Statistically significant differences in HRQOL between treatment groups were studied in 69% studies, but the clinically meaningful difference was examined in only one study. Prognostic value of QoL was assessed in only two trials (15%). Most widely observed methodological issues included lack of priori hypothesis (92%) and lack of methods to deal with missing data (85%). Other issues included lack of details on domain, variability in time points of assessment of a trial, and patient’s noncompliance, reported in ~60% studies. CONCLUSIONS: HRQOL is included as an outcome in the studies investigating treatments in cervical carcinoma but clinically meaningful interpretations of HRQOL results are rarely considered. The methodological shortcomings in the assessment and analysis of HRQOL outcomes should be examined further to derive clinically meaningful and correlating evidence.

**PCN/132**

**ERLOTINIB MAINTENANCE THERAPY FOR NON-SMALL CELL LUNG CANCER PRESERVES QUALITY OF LIFE**

Jabbari E1, Kim JH2, Stelmakh L3, Cicianas S4, Königshain G1

*Onagador Kardi TBC, Budapest, Hungary; 2St. Vincent’s Hospital, Seoul, South Korea; 3F. Hoffmann-La Roche Pharmaceuticals AG, Basel, Switzerland*

OBJECTIVES: Maintenance therapy can delay progression and prolong survival in metastatic non-small cell lung cancer (mNSCLC). The impact of treatments for patients with mNSCLC on quality-of-life (QoL) is an important consideration. However, the utility of QoL measurement is noncurative and QoL in this population is already compromised. The SATURN study demonstrated that, compared with placebo, erlotinib maintenance therapy improved progression-free survival and overall survival by 41% and 23%, respectively. The impact of erlotinib maintenance therapy on QoL was also evaluated at a secondary end point. METHODS: Patient QoL was assessed until disease progression or withdrawal using the Functional Assessment of Cancer Therapy-Lung (FACT-L) questionnaire. Disease progression was assessed radiographically at regular intervals, often diagnosed prior to symptomatic progression. Patient QoL was assessed in terms of...