ate for patient reporting in their current form, due to mixing of symptom attributes within items and technical jargon. The committee determined that measured attributes for each symptom should include frequency, severity, and activity interference. Questions and response options were standardized, along with plain language terms for each symptom. a web-based platform was developed for administering the new PRO-CTCAE items. **CONCLUSIONS:** In response to a charge from the NCI, the PRO-CTCAE, a patient version of the CTCAE system, has been developed. The prototype is undergoing testing to assess validity, usability, and logistical feasibility in a variety of cancer care settings. The PRO-CTCAE system has the potential to enhance adverse event reporting by integrating patient experiences and can foster consistency of data collection methods across studies.

**PCN123**

## DEVELOPMENT OF A COMPUTER-ADAPTIVE PATIENT REPORTED OUTCOME TOOL FOR THE SCREENING FOR PSYCHO-ONCOLOGICAL TREATMENT NEEDS

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**OBJECTIVES:** Diagnosis and treatment of cancer entail a considerable amount of distress which in a large percentage of patients would require psychooncological 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-adpative testing (CAT) version. **METHODS:** 115 breast cancer outpatients attending the Department of Gynaecology at Innsbruck Medical University 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 105 breast cancer patients (mean age 58.8, SD 12.3) were analyzed. The EORTC QLQ-C30 scales Emotional Functioning and Role Functioning as well as the yes–no question after psychiatric/psychological/psychotherapeutic 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 prelinimary items which will be subjected to further analyses. **CONCLUSIONS:** The implementation of precise and effective measures for POT needs 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**

## COMPUTER-ADAPTIVE TESTING OF FATIGUE IN ONCOLOGICAL PATIENTS

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**OBJECTIVES:** Computer-adaptive testing (CAT) is an advanced method for measuring patient-reported outcomes. With help of an algorithm, CAT selects the items most relevant for an individual patient from an item bank. Our study aim was the development of a CAT version of the EORTC QLQ-C30 Fatigue scale, its implementation in a software package, and its use in daily clinical routine. **METHODS:** Our project is part of a large project on CAT development conducted by the EORTC Quality of Life Group. To set up an initial English fatigue item list, an extensive literature research was performed. These items were refined through multistage expert reviews, translated to German, Danish, Spanish, French, and Dutch, and filled in by a pilot patient sample to collect feedback. In a next step, a large patient sample is recruited for all language versions to gain data for development of the item bank and the CAT algorithm. **RESULTS:** Literature research resulted in 588 fatigue items, from which 44 were selected after comprehensive expert reviews. Based on feedback from 52 oncological patients, wording and translation of several items were revised. Data have been collected from about 1200 patients. Preliminary results of the CAT-analysis will be presented. **CONCLUSIONS:** By generating individually tailored item sets, CAT reduces patient burden and assessment duration, and increases measurement precision. In addition, electronic data capture increases data quality and reduces the amount of human resources required for data collection.

**PCN125**

## ECONOMIC AND PATIENT-REPORTED OUTCOMES OF OUTPATIENT HOME-BASED VERSUS INPATIENT HOSPITAL-BASED CHEMOTHERAPY FOR PATIENTS WITH COLORECTAL CANCER

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**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 FOLFOX 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 higher score indicating higher satisfaction) than did those treated at the hospital (3.23 ± 0.21; $P < 0.01$). After adjusting for differences in baseline characteristics between the two groups using multivariate analysis, those receiving home-based chemotherapy still showed significantly higher satisfaction than those undergoing hospital-based therapy ($\beta = 0.271$, $P < 0.001$). 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.

**PCN126**

## REVIEW OF PATIENT-REPORTED OUTCOMES IN PHASE II ONCOLOGY CLINICAL TRIALS

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**OBJECTIVES:** Patients' own assessment of the impact of anticancer therapy has been considered important from a patient, physician, payor, and regulatory perspective. Approximately 12% of all oncology clinical trials list at least one patient-reported outcome (PRO) measure; 50% of these are phase II trials. Use and publication of PROs results were systematically reviewed for breast, colorectal, ovarian, and non-small cell lung cancer (NSCLC). **METHODS:** Citeline's TrialTrove database was searched for oncology trials that included PROs and were planned, ongoing or completed as of October 2009. Specific trial factors examined include phase, disease type, location, sponsorship, type of PRO instrument(s), and publication of PRO endpoint results. **RESULTS:** Of the 5483 phase II trials retrieved for breast, colorectal, ovarian, and NSCLC, 9% listed PROs. PRO measures were more frequently included in NSCLC (13%) and ovarian cancer (10%) than in breast (7%) or colorectal (8%) cancer phase II trials. Fifty-two percent of these trials were sponsored by industry, with 25% and 19% being sponsored by academic and cooperative groups, respectively. One-third of the trials were conducted in the United States only. PROs were most frequently measured with the EORTC and FACT series of questionnaires. Phase II PRO results were published 24%, 36% and 39% of the time for breast, ovarian, and NSCLC, respectively, and only 18% of the time for colorectal cancer. This compares with an overall publication frequency for PRO trials (any end points) of 58% to 67% which was highest in NSCLC. PRO results were published more frequently for trials conducted in Asia or Europe. However, trial sponsorship did not impact publication frequency. **CONCLUSIONS:** PROs are infrequently assessed in phase II cancer trials. PRO measures were most frequently included in NSCLC trials and sponsored by industry. PRO results were published less frequently than other end points in these trials. Publication frequency differed by tumor type and trial location.

**PCN127**

## MINIMAL CLINICALLY MEANINGFUL DIFFERENCES FOR THE EORTC QLQ-C30 AND EORTC QLQ-BN20 SCALES IN BRAIN CANCER PATIENTS

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**OBJECTIVES:** The aim of this study was to determine the smallest changes in health-related quality-of-life (HRQOL) scores in the European Organization for Research and Treatment of Cancer quality of life questionnaire (EORTC QLQ-C30) and the EORTC Brain Cancer Module (QLQ-BN20), which could be considered as clinically meaningful in brain cancer patients. **METHODS:** World Health Organization (WHO) performance status (PS) and the Mini Mental State Examination (MMSE) were used as clinical anchors appropriate to related subscales to determine minimal clinically important differences (MCID) in HRQOL change scores (range 0–100) in the EORTC QLQ-C30 and QLQ-BN20. a threshold of 0.2SD (small effect) was used to exclude anchor-based MCID estimates considered too small to inform interpretation. **RESULTS:** Based on WHO PS, our findings support the following integer estimates of the MCID for improvement and deterioration, respectively: physical functioning (6, 9), role functioning (14, 12), cognitive functioning (8, 8), global health status (7, 4*), fatigue (12, 9), and motor dysfunction (4*, 5). Anchoring with MMSE, cognitive