

## Abstracts

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instrument has five functional scales (physical, role, cognitive, emotional, and social), three symptom scales (fatigue, pain, and emesis), and a global health/quality of life scale. The remaining single items assess dyspnoea, appetite loss, sleep disturbance, constipation, and diarrhoea. The analyses focused on intraclass correlation coefficients (ICCs), comparing the ICC 95% lower confidence interval with a critical value of 0.70. **RESULTS:** Subjects who did not complete the second assessments within 72 hours or who had score differences on the scales or items exceeding two standard deviations were excluded from the per protocol analyses. The sample sizes used in the per protocol analyses ranged from 112 to 115 subjects. The ICCs for the 9 multi-item scales were all above 0.69, ranging from 0.698 to 0.926 (ICC 95% lower CI range: 0.608 to 0.901). All of the scales were significantly different from our threshold reliability of 0.70, with the exception of the cognitive functioning scale. The ICCs for the 6 single items ranged from 0.782 to 0.908 (ICC 95% lower CI range: 0.714 to 0.876) and all were statistically different from 0.70. The evidence supports the stability of the scores obtained on the IVR version of the QLQ-C30 upon repeated measurement. **CONCLUSIONS:** The equivalence of the IVR and paper versions of the QLQ-C30 has been demonstrated elsewhere. This analysis provides additional evidence of the test-retest reliability of the IVR version of the QLQ-C30.

PCN88

#### LEVERAGING PATIENT-REPORTED OUTCOMES TO DEFINE FATIGUE IN CANCER

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**OBJECTIVES:** Research indicates 18% to 96% of cancer patients experience fatigue due to cancer or its treatment. Only one claim for "cancer-related fatigue" (CF) has been granted by the US Regulatory Authorities. To date, the definition or diagnosis of CF remains a subject for debate within the clinical community. Although several self-completed CF-specific instruments are available, the lack of an accepted conceptual framework articulating those concepts important to patients has hampered research in this field. Developing a preliminary conceptual framework able to underpin patients' experience of CF is central to gather meaningful data. Qualitative articles with verbatim patient quotes were reviewed and synthesized to begin a large effort to develop such a framework. **METHODS:** A systematic search identified 95 articles published between 1996 and 2007 containing patient quotes. Search terms included fatigue, tiredness, lassitude, weakness, or asthenia. Two researchers independently reviewed articles; 645 quotes were extracted and systematically analyzed to identify concepts and language used to describe patients' CF experiences. **RESULTS:** CF is more intense than pre-diagnosis or treatment tiredness. Terms such as "overwhelming," "unusual," and "all-encompassing" were used to describe CF. Quotes referring to "tiredness" were often associated with adverbs (very, extremely) or patients' idiomatic phrases intensifying "tiredness" (e.g., "dead-tired", "sick-tired") to distinguish tiredness due to CF. Metaphors depicted the severity and debility associated with CF. **CONCLUSIONS:** Findings suggest that extant CF assessments fail to capture the unique experience of CF as described by patients. Publication bias and lack of primary data from which quotes were drawn are study limitations. Rigorous qualitative research with patients with different types and stages of cancer is needed to concisely and comprehensively describe the experience of CF and its impact.

PCN89

#### FACTORS IMPACTING THE HEALTH RELATED QUALITY OF LIFE IN FEMALE BREAST CANCER PATIENTS – AN OBSERVATIONAL, CROSS-SECTIONAL STUDY

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**OBJECTIVES:** To estimate the impact of performance status (ECOG), age, concomitant conditions, length of diagnosis, exposure to chemotherapy treatment and caregiver need on health related quality of life (HRQoL) in 800 adult female breast cancer patients in the USA and 5 European countries (France, Germany, Italy, Spain and UK). **METHODS:** Data were drawn from the Adelphi Breast Cancer Disease Specific Programme (DSP), a cross-sectional study of consulting patients, undertaken in 2007. Physicians collected data on the next 7 patients presenting with breast cancer during the study period. Patients were asked to report on their HRQoL (FACT-B). OLS regressions were performed using STATA. Diagnostic tests were performed (joint significance, misspecification and multicollinearity) and White standard errors were applied. **RESULTS:** Eight hundred (Europe, 686; USA, 114) patient records were analysed. FACT-B scores were significantly impacted in line with worsening ECOG performance status (Grade 1: -7.44, overall; -5.94, USA; -13.48, Europe; all  $p < 0.001$ ; Grade 2: -14.92, overall; -13.45, USA; -19.39, Europe; all  $p < 0.001$ ; Grade 3: -22.04, overall; -20.87, USA; -21.94, Europe; all  $p < 0.001$ , except USA,  $p < 0.05$ ). No Grade 4 patients were present in the sample. FACT-B scores were lower overall and in Europe, in patients currently receiving chemotherapy (-9.13, overall; -9.78, Europe; all  $p < 0.001$ ), those with a caregiver (-5.64, overall; -7.05, Europe; all  $p < 0.001$ ). Longer diagnosis (+0.82,  $P < 0.05$ ) and presence of mental health related concomitant conditions (-7.25,  $P < 0.05$ ) were significant in US patients only. Age and heart related concomitant conditions were not significant. Models showed overall robustness to the diagnostic tests performed. **CONCLUSIONS:** A significant association was seen between the patient-reported FACT-B scores and the physician-reported ECOG performance status. The impact of the various factors identified, including chemotherapy use, mental health related concomitant conditions and time since diagnosis, can provide useful indicators to be taken into account in the management of breast cancer patients.

#### A METHODOLOGICAL INVESTIGATION TO DEFINE A CLINICALLY RELEVANT CUT-OFF POINT IN THE ORDINAL SCALE OF THE EORTC QLQ-C30 QUESTIONNAIRE

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**OBJECTIVES:** The objective of this analysis was to develop a new analytic methodology to identify a clinically relevant cut-off point in the EORTC QLQ-C30 ordinal pain score by comparing patient and clinician reporting for the same symptom. Ability to translate between clinician and patient reported symptoms will be useful in planned future analyses. **METHODS:** Closed European Organisation for Research and Treatment of Cancer Randomized Controlled Trials, where the symptom pain was scored at baseline by the patient (EORTC QLQ-C30) and the clinician [Common Toxicity Criteria (CTC)], were pooled and analysed to test the optimal cut-off point. The CTC was dichotomized as 0,1,2 vs. 3,4; defined as a clinical relevant cut-off point for clinical practice. Percent agreement with various dichotomizations of the QLQ-C30 pain scale was calculated, and McNemar's test applied. Verification of the accuracy and generalizability of the findings was evaluated with a validation set and by applying the same cut-off point on another symptom, i.e. fatigue. **RESULTS:** Data were available for pain [number of trials (t) = 8, number of patients (n) = 1214] and fatigue [t = 5, n = 1237]. Model and validation set were obtained by splitting the dataset in half. Percentage agreement and p values for McNemar tests, between patient and clinician dichotomized scores using different cut-off points for the QLQ-scale, were: median (<2.19 vs. >2.19, 64%,  $p < .01$ ), quartile (<=vs. >3.0, 81%,  $p = 0.55$ ), decile (<4.0 vs. 4.0, 85%,  $p < 0.01$ ). The quartile split reflects best the dichotomized CTC score. This was confirmed in the validation set (quartile cut-off point: 82%,  $p = 0.86$ ). However, when the quartile cut-off was applied to the QLQ-C30 fatigue scale, a significant difference ( $p < .01$ ) between patient and clinician results was found. **CONCLUSIONS:** Our results indicate that a quartile split of the QLQ-C30 pain score is optimal. However, a single cut-point may not generalize to other QLQ-C30 symptoms; symptom-specific cut-points may be required.

PCN91

#### PROVISION OF QUALITY OF LIFE INFORMATION AND PHYSICIAN TRUST AMONG FAMILIES OF CHILDREN WITH LIFE-LIMITED CONDITIONS

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**OBJECTIVES:** To examine what information that parents of children with life-limiting conditions want from physicians and whether the provision of this information promotes parents' trust in physicians. **METHODS:** We conducted telephone surveys from November 2007 through April 2008 with a random sample of 266 parents whose children had life-limiting conditions and enrolled in Florida's State Title V Children with Special Health Care Needs Program. Parents were asked if they wanted information about the following: the child's quality of life, pain relief, prognosis, incorporating spiritual beliefs into the treatment plan, how treatments might change the child's appearance, and clinical examination/laboratory results. We used the Wake Forest Physician Trust Scale to measure parent's trust in physicians. We tested the relationships between parent's age, race/ethnicity, education, marital status, and parent-reported children's health status and desired information. We also tested whether provision of this desired information was associated with greater trust in physicians. **RESULTS:** Most parents wanted information on their children's quality of life (95%), followed by the prognosis (88%) and pain relief (84%). Forty-nine percent of the parents desired advice from family/friends. Compared to parents with a high school education or higher, parents with less than a high school education showed a greater desire for information on pain relief and spiritual belief ( $p < 0.05$ ). Compared to White non-Hispanic parents, Hispanic and Black non-Hispanic parents showed a greater desire for information on the child's prognosis, incorporating spiritual beliefs into the treatment plan, and the impact of the treatment on the child's appearance ( $p < 0.05$ ). Providing information on children's quality of life and pain relief was associated with greater trust in physicians after adjusting for parental characteristics ( $p < 0.05$ ). **CONCLUSIONS:** Parents wanted information on their children's quality of life more so than any other information category. Providing this information along with information about pain relief increased the families' trust in the physicians.

PCN92

#### HOW DOES TRUST IN PHYSICIANS AFFECT PARENTS' TREATMENT DECISION MAKING FOR THEIR CHILDREN WITH LIFE-LIMITING CONDITIONS?

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**OBJECTIVES:** To examine the association between characteristics of parents whose children are diagnosed with life-limiting conditions, trust in physicians, and problems in the shared decision making process. **METHODS:** This study using data collected