emotions (p = 0.048, p = 0.015). CONCLUSION: As expected, the patients had lower HRQOL and increased emotional morbidity when neutropenic. Parental reports provide evidence that the Turkish translation is acceptable, understandable and has construct validity for assessing health-status in childhood cancer patients.

**PCN56**

**RELATIONSHIP BETWEEN FUNCTIONAL STATUS AND SELF-RATED HEALTH IN PATIENTS WITH PROSTATE CANCER:**

**DATA FROM CAPSURE**

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OBJECTIVES: The functional status of individuals and their self-rated quality of life has been shown to be an important predictor of general quality of life, mortality, and utilization of health services. We investigated the factors associated with physical function (PF) and general health (GH) at baseline in patients with prostate cancer as well as factors associated with changes over the course of disease. METHODS: Data from CAPSURE, a longitudinal disease registry of men with prostate cancer, was used to identify a group of men who were newly diagnosed with prostate cancer, have defined initial treatment, and had one pretreatment and at least two years of post-treatment HRQOL assessments. HRQOL were measured by SF-36 and were assessed bi-annually. Changes in PF and GH scores over time were evaluated by mixed model analysis, accounting for type of treatment received, time of HRQOL assessment, age, diagnosis, level of function at baseline, and education level. RESULTS: 3625 patients met the study criteria. At baseline high level of physical functioning and general health (median 95 and 75 respectively) were demonstrated. In multivariate mixed model analysis, type of treatment, baseline level of physical function, time of HRQOL assessment, age, education level, and interaction term between time and type of treatment were significantly associated with changes in PF and GH over time. Differences in PF and GH persisted throughout the period of study and varied greatly depending on level of function at baseline (adjusted means 62.7 vs. 95.2 for PF and 62.1 vs. 78.0 for GH at first year after treatment). CONCLUSION: Further evaluation of the relationship between GH and PF can provide us with important information to identify critical elements of HRQOL. Identification of the specific determinants of perceived and objective measure could provide us with tools for improving overall quality of life in patients with prostate cancer.

**PCN57**

**PATIENT REPORTED OUTCOMES IN LABELING FOR ONCOLOGY PRODUCTS: REVIEW OF FDA AND EMEA LABELS**

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OBJECTIVES: To review the oncology products approved in the United States and in Europe with a particular focus on the Patient-Reported Outcome (PRO) endpoints appearing in the products’ labels. METHODS: Oncology products approved in Europe since 1995 through the centralized procedure and in the United States since 1998 (new molecular entities) were identified directly from our internal resources resulting from a review of the EMEA and FDA websites. Using the PROLabels database, we identified the products indicated for cancer treatment and showing evidence of PRO in labeling. PRO Labels is a unique on-line tool which provides information on the drug products for which the FDA and/or the EMEA have granted a PRO labeling claim. RESULTS: Overall, 36 different products indicated for the treatment of cancer were identified in this review, 12 of which were approved both in Europe and in the U.S. Of these 36 approved drugs, 7 contained descriptions of Patient-Reported Outcomes in the labeling. Two drugs were approved in the US with PRO data used to assess health-related quality of life (HRQL), treatment satisfaction and subjective assessment of lesions. In Europe, 5 products used PRO data to capture HRQL, pain, and symptoms. These products were different from the US ones. Regarding the methods to measure PRO, 5 products used a defined instrument, one used a single item and another used a questionnaire which was not specified. CONCLUSION: Overall, PRO data in labeling for oncology products is not frequent (between 8 and 20% of approved products), and is comparable with the average rate over all therapeutic areas (source PROLabels). The location of PRO endpoints was mainly in the clinical studies section. An interesting finding is the lack of overlap between the American and the European PRO claims.

**EAR/EYE—Clinical Outcomes Studies**

**PEY1**

**COMPARISON OF TOPICAL CIPROFLOXACIN/DEXAMETHASONE OTIC SUSPENSION VERSUS POLYMYXIN B/NEOMYCIN/HYDROCORTISONE OTIC SUSPENSION FOR THE TREATMENT OF ACUTE OTITIS EXTERNA**

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OBJECTIVES: The objective of this study was to compare ciprofloxacin 0.3%/dexamethasone 0.1% (CD) otic suspension to polymyxin b/neomycin/hydrocortisone (PNH) otic suspension for the treatment of acute otitis externa (AOE). METHODS: Data from two randomized AOE clinical trials were pooled together for this analysis. AOE patients randomly received either CD, 3–4 drops twice a day for seven days, or PNH, 3–4 drops three times a day for seven days. Clinical assessment of ear inflammation, ear tenderness, ear edema and ear discharge were performed on days 3, 8 and 18 of the study. Inflammation and edema were evaluated using the following four point scale: none = 0, mild = 1, moderate = 2, severe = 3. Ear tenderness and otic discharge were rated on a scale where absent = 0 and present = 1. A composite clinical score with a range of 0 to 8 was used as the final outcomes measure. Clinical cure was defined as composite clinical score of zero. A Kaplan-Meier survival analysis with a log-rank test was used to compare the cure rates between treatment groups. RESULTS: A total of 1072 patients (1242 ears) were included in the analysis (537 CD patients and 535 PNH patients). Both treatment groups were similar with respect to baseline AOE severity and demographic parameters. The log-rank test revealed a significant (p = 0.0380) difference in AOE cure rates between the CD and PNH groups. The Kaplan-Meier analysis indicated that CD patients were cured 0.6 days sooner than PNH patients (9.7 versus 10.3 days, respectively) and the time needed to cure 75% of the CD group was 8 days compared to 18 days for the PNH group. CONCLUSION: CD appears to be superior to PNH for the treatment of AOE due to its faster cure rate.