with assessing who might benefit from treatments such as prophylactic G-CSF. **METHODS:** The literature review included publications from 1990–2000 of adults with any tumor type; 121 articles were identified that referenced risk factors or predictors for severe/febrile neutropenia. Study design, patient characteristics, chemotherapy treatment, and incidences of neutropenia were recorded. **RESULTS:** Twenty-one relevant publications, including prospective, retrospective, and modeling studies, were further analyzed. These articles yielded 27 potential risk factors/predictors in 3 categories: patient (n = 14), treatment-related (n = 8), and disease-related (n = 5) characteristics. Although most of the 27 potential risk factors/predictors were not validated to identify patients at higher risk for severe/febrile neutropenia, the review suggests that several simple-to-use and commonly available risk factors may be reliable predictors of neutropenia. These included low hemoglobin and neutrophil counts in cycle one; depth of the neutrophil nadir; low lymphocyte, monocyte and platelet levels; and a precipitous, early drop in blood cell counts. Several other risk factors, such as serum albumin ⩽3.5g/dL on day 1, serum LDH >1× normal alone or combined with bone marrow involvement, and high dose chemotherapy, also warrant further investigation. **CONCLUSIONS:** Few studies have explicitly explored risk factors associated with the occurrence of Grade 3–4 neutropenia. However, this literature review identified several common characteristics that may be measured with early and frequent CBC monitoring and may reasonably predict predisposition of patients to severe/febrile neutropenia.

PCN4

COMPARING MEAN VERSUS MEDIAN SURVIVAL AS A PRELUDE TO COST-EFFECTIVENESS (C/E) ANALYSES

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BACKGROUND: In a multinational trial designed to determine the efficacy of epoetin alfa in chemotherapy-induced anemia, patients receiving non-platinum chemotherapy having a hemoglobin 10.5 g/dL or less, or a decline in hemoglobin of 1.5 g/dL or greater were randomized (2:1) to epoetin alfa or placebo. A total of 375 patients (251 epoetin alfa, 124 placebo) were assessed for survival status twelve months after completing the protocol, but prior to unblinding. A log-rank test showed a trend in survival favoring epoetin alfa (median of 17 vs. 11 months, p = 0.128). **OBJECTIVES:** The primary efficacy endpoint for many cancer clinical trials is median survival. In preparing for an economic analysis, however, we analyzed mean survival, the appropriate survival endpoint for a C/E analysis. **METHODS:** Sampling with replacement, we conducted a post hoc analysis that examined the difference in mean survival by drawing 10,000 samples in a bootstrapping simulation. Within each sample the survival curves were truncated to maintain identical follow-up periods between treatment groups. The difference in mean survival was computed for each sample. The probability of superior efficacy was obtained by sorting the results from the samples. **RESULTS:** The average mean survival difference, across the 10,000 samples, showed a 0.212-year survival benefit for epoetin alfa. The probability that the difference in mean survival favors epoetin alfa was 0.965. **CONCLUSIONS:** Comparing differences in median and mean survival may lead to different conclusions about the value of a therapy. Given that mean survival is the appropriate effectiveness endpoint for survival-based C/E analyses, a non-significant difference in median survival does not preclude full C/E analyses. Specifically, the mean survival results from this trial warrant a full C/E analysis of epoetin alfa in treating anemia for patients receiving non-platinum chemotherapy.

PCN5

DOCETAXEL/DOXORRUBICIN (DD) AS FIRST LINE CHEMOTHERAPY: QUALITY OF LIFE (QOL) IN PATIENTS (PTS) WITH METASTATIC BREAST CANCER (MBC)

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OBJECTIVE: In spite of initial treatment of MBC with DD showed high level of efficacy expressed as improved disease-free interval, time to relapse and overall response, it remains as a palliative one. Because of there is some evidence that QOL is improved with this treatment, we designed the study to investigate the impact and changes on QOL in patients (pts) with MBC treated with DD, and its relationship with clinical parameter of response. Material and METHODS: Between July 1999 and July 2000, we treated 42 MBC pts with doxorrubicin 50mg/m2 and docetaxel 75 mg/m2, i.v., day 1. Inclusion criteria: female between 18–75 years old, ECOG PS 0-2, and stage IV of MBC histologically confirmed. QOL was assessed at baseline and prior to the first, third and fifth cycle of chemotherapy with the EORTC QLQ-C30 version 2.0, an integrated measurement system to evaluate QOL of cancer pts. **RESULTS:** To date, 33 pts (median age = 51.7; range 40–67) with available data, have completed 5 cycles of chemotherapy. Repeated measures analysis of variance (MANOVA) showed time effects statistically significant (p < 0.5) for Emotional Functioning (EF; p = .001), and Cognitive Functioning (EF; p = .001) scales, and pain (p = .000), insomnia (p = .05) and constipation (p = .02) symptom scales. When baseline QOL was compared with that after 5 cycles (paired t-test), it was observed significant improved in EF (p = .003), pain (p = .005) and Insomnia (p = .04). We grouped pts with CR and PR (n = 14) for comparing with SD pts (n = 19) and we observed significantly improve in the first group after the fifth cycle, in physical functioning (p = .05) and social functioning (p = .005). **CONCLUSION:** These preliminary data suggest that pts with MBC undergoing DD chemotherapy experience improvement in several QOL pa-

rameters, showing correlation with the clinical response achieved. There were significant changes in major components of QLQ-C30 in pts who achieved clinical response.

PCN6

CAN ICD-9 CODES BE USED AS A PROXY FOR DISEASE STAGING IN ECONOMIC EVALUATIONS?

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Administrative health care databases are increasingly used as a source of data for economic studies in cancer. In order to adjust for disease severity, several investigators have utilized ICD-9 codes indicating metastases as a proxy for cancer staging. **OBJECTIVE:** To determine the validity of using ICD-9-CM codes indicating metastases as a proxy to classify lung cancer patients by stage of disease. **METHODS:** This retrospective database analysis used diagnosis codes to classify subjects to either localized or advanced stage disease and then compared this classification to the tumor registry staging, which was considered as the "gold standard". Study subjects included all lung cancer patients treated at an academic institution during 1996–97 who were also members of a large insurance company. Data was derived from inpatient cancer-related claims linked with the institution's tumor registry data. Advanced stage disease (stages II to IV) was defined by claims indicating lymph node involvement or metastases (ICD-9 codes 196-199.1). The tumor registry staging of the disease for these patients were clustered into two groupings, stages 0–I (localized) and stages II–IV (advanced). **RESULTS:** Tumor registry entries were identified for 85.7% of patients. The crude concordance between the claims and tumor registry classifications was 74.2% (Kappa coefficient = 0.4848). The positive predictive value of identifying localized disease utilizing ICD-9 coding was 57.6%,while the predictive value of a negative test was 91%. The sensitivity and specificity for dichotomized disease stage was 86.4% and 68.2% respectively. **CONCLUSIONS:** For a population of lung cancer patients in an academic institution, the use of ICD-9 coding was associated with modest predictability for disease staging. The use of ICD-9 coding as a proxy for disease staging in economic evaluations should be executed with caution.

PCN7

ECONOMIC EVALUATION OF GEMZAR AND BEST SUPPORTIVE CARE (BSC) RELATIVE TO BEST SUPPORTIVE CARE ALONE IN THE TREATMENT OF NON SMALL CELL LUNG (NSCLC) CANCER IN THE UK

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OBJECTIVES: Lung cancer is a leading cause of morbidity and mortality. Chemotherapy is one of the main treatment options but its availability in the UK is limited in comparison to other countries, is inconsistent across geographical regions, with many patients receiving only palliative care. The present study reports results of an economic evaluation of Gemzar (one of the newer agents available) and best supportive care (BSC) relative to BSC in the treatment of advanced NSCLC. BSC relates to all forms of care which are non-curative in intent excluding chemotherapy. **METHODS:** The study is undertaken from the perspective of the UK NHS. Data were extracted from a comparative trial undertaken in the UK (Anderson et al in 1997). Cost estimates are based on: chemotherapy and associated infusion, hospitalisations, health care professional visits, concomitant medications, radiotherapy and terminal palliative care. Resource utilisation data from the clinical trial were combined with unit-cost data from various UK sources. Costs are presented in 2000 price levels and the time horizon for their estimation is one year; hence discounting was unnecessary. Treatment effectiveness is measured by progression-free survival and tumour response. Extensive sensitivity analysis was also performed. **RESULTS:** Total treatment cost per patient in the Gemzar/BSC arm was estimated at £5,502 and at £3,861 for the BSC arm, the difference attributed mainly to the drug (Gemzar) and its administration costs. The intervention arm had lower radiotherapy/concomitant medication costs, but this did not offset the drug acquisition cost. Progression free life years and overall tumour response rates were 0.789 and 18.5% in the Gemzar/BSC arm and 0.474 and 0% in the BSC arm. The incremental cost-per-progression-free-life-year gained in Gemzar/BSC relative to BSC is £5,228 and the incremental cost-per-tumour-response £8,873. Changes in the key variables varied the above ratios between £3,000 and £23,000. **CONCLUSIONS:** The economic evaluation presented above shows that Gemzar/BSC is a cost-effective therapy for advanced NSCLC relative to BSC alone.

PCN8

ECONOMIC EVALUATION OF GEMZAR IN THE TREATMENT OF PANCREATIC CANCER IN THE UK

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OBJECTIVES: Pancreatic cancer is a significant and increasing cause of morbidity and mortality in the UK. Treatment with chemotherapy has shown to improve symptoms and survival of patients. Gemzar is licenced for treatment of pancreatic cancer in the UK. This study reports on an economic evaluation of Gemzar relative to 5-FU, a commonly used regimen for advanced pancreatic cancer patients in the UK. **METHODS:** The perspective is that of the UK-NHS. Data were derived from a clinical