DISEASE MODELING: DEVELOPING THE INFRASTRUCTURE FOR A COMPREHENSIVE, MULTI-NATIONAL, CLINICAL AND ECONOMIC BREAST CANCER TREATMENT MODEL
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OBJECTIVES: To develop the cost data infrastructure to support a comprehensive, multi-national breast cancer treatment decision-analysis model. The specifications required a user-friendly interactive interface for over 70 comparators composed of nearly 350 cost components used in 24 unique decision trees. The model required an ability to vary components readily and add new treatments and cost components to multiple trees. METH-ODS: Since standard decision-analysis software doesn’t permit categorization of variables or application of the same variable to multiple decision trees: (1) trees were programmed in Visual Basic for the interactive interface, and (2) cost data were loaded into a Microsoft ACCESS database linked to the trees. Because of this structure, it was possible to categorize cost data as: 1) Drug Acquisition and Administration, 2) Adverse Events/Complications, 3) Concomitant Medications, 4) Hospitalizations, and 5) Monitoring Costs. For each country in the model, a separate database was developed with country-specific costs obtained from standardized databases, government sources, published literature, and a provider survey. RE-SULTS: This model was developed for six countries—US, U.K., Germany, Japan, France, and Italy—and included clinical and economic variables related to the diagnosis, treatment, and outcomes of breast cancer. The structure permits dynamic analyses via varying cost and probability scenarios that reflect country-specific treatment practices and international variations. Each country’s cost database applies to four distinct decision trees representing different stages of breast cancer. The costs can be easily summarized by category and modified so that multiple cost components in multiple trees can be varied with one edit. New cost components can be added to each country’s database and linked to the trees. CONCLUSION: When constructing large models (such as disease models) with several treatments having common cost components in multiple decision trees, using a categorized cost database linked to the treatment pathways will generate a user-friendly model with easily-varied cost inputs.

INCIDENCE AND COST OF HOSPITALIZATION FOR 5-FU TOXICITY AMONG MEDICARE BENEFICIARIES WITH METASTATIC COLORECTAL CANCER
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BACKGROUND: While treatment with 5-fluorouracil (5-FU) plus leucovorin has been shown to prolong survival in patients with metastatic colorectal cancer, it also can cause significant toxicity, sometimes necessitating hospitalization. The incidence and costs of these admissions have not been fully documented. OBJECTIVE: To estimate the incidence and cost of hospitalizations for toxicities associated with 5-FU therapy in patients with metastatic colorectal cancer. METHODS: Using the 1994 Medicare 5% sample, we identified all patients with metastatic colorectal cancer who underwent colorectal surgery. We stratified these selected subjects into those who received 5-FU therapy within 90 days of their surgery (“5-FU group”) and those who did not receive any chemotherapy (“no-chemotherapy group”); patients receiving chemotherapeutic agents other than 5-FU were dropped from the sample. Using techniques of survival analysis, we then compared the incidence and cost of all hospital admissions with listed ICD-9-CM diagnosis codes (principal or secondary) for conditions that may be related to 5-FU toxicity (e.g., volume depletion, stomatitis, nausea and vomiting). RESULTS: A total of 441 patients met all study entry criteria, including 192 who received 5-FU and 249 who did not receive chemotherapy following surgery. 5-FU patients were significantly younger than those in the no-chemotherapy group (p < .001). Mean (±SD) follow-up time was slightly longer in the 5-FU group (137 ± 96 days vs 117 ± 88 days for no chemotherapy). The incidence at 10.5 months of toxicity-related hospitalizations (principally volume depletion, agranulocytosis, gastroenteritis, and nausea and vomiting) was 31% among patients who received 5-FU and 8% among those who did not receive chemotherapy. The cost of inpatient care was $2,716 higher among 5-FU patients. CONCLUSIONS: Hospitalization for 5-FU toxicity is frequent and costly among Medicare patients with metastatic colorectal cancer.

A QUALITY OF LIFE AUDIT OF PATIENTS WITH NON-SMALL CELL LUNG CANCER HAVING CHEMOTHERAPY AT ONE INSTITUTION
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OBJECTIVES: Establish the impact that present chemotherapy management is having on the quality of life (qol) of patients being treated at the Prince Charles Hospital; allow comparison of the effect on the patients qol between established treatment modalities; allow comparison of the effects on patients qol between established and future trial treatment protocols. We report the interim findings of this ongoing quality of life study. METHODS: All patients referred for chemotherapy management of their non-small cell lung cancer (NSCLC) were asked to participate. The EORTC QLQ 30 and LC 13 were used to assess patients qol when disease restaging tests were conducted. Data was entered into an access database that allowed comparison. Protocols used were CIV, CV-adjuvant-neoadjuvant setting. CG and single agent Gemcitabine 1000mg/m2 on days 1, 8, 15, in the palliative setting. RESULTS: Patients ages ranged 39 to 73 yrs, average age 53 yr, median, 51, mode 47yrs. The sample consisted of 3 females & 12 males, 6 patients are not reported, 3 neoadjuvant had progressive disease after two cycles and were not followed, 3 palliative patients died after one cycle of treatment. Of the 21 patients treated 15 (71%) had improved Quality of Life scores paralleled other measures of assessment. Scans show response to single agent Gemzar in the palliative setting and response to CIV in the neoadjuvant setting. CONCLUSION: we demonstrated 71% of our patients had qol improvements. Management of patients with NSCLC should consider chemotherapy. FUTURE DIRECTION: An outcomes study is being conducted at two campuses in Brisbane. This study seeks to include all newly diagnosed lung cancer patients and follow their progress through their disease using clinical Quality of Life and economic criteria to determine outcome. Comparison between treatment and within treatment arms will be compared.

SYSTEMATIC ASSESSMENT OF HEALTH-RELATED QUALITY OF LIFE INSTRUMENTS FOR USE IN CLINICAL TRIALS OF NON-SMALL CELL LUNG CANCER
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OBJECTIVE: To critically evaluate the quality of health-related quality of life (HRQoL) instruments for use in clinical trials of non-small cell lung cancer (NSCLC). METHODS: A structured review of literature was conducted by searching MEDLINE (1975–2000) and PsyclINFO (1977–2000) using the keywords “lung cancer”, “quality of life” and “questionnaire”, and manually. HRQoL instruments that had been used in or designed for lung cancer were selected for review. Each instrument was assessed for its general features, feasibility, scoring and interpretation, and psychometric properties. RESULTS: Ten instruments were selected for review: EORTC-QLQ30, EORTC-LC13, FACT-L, LCSS, FLIC, CARES, CARES-SF, RSCL, FLIC and MQOL. Most questionnaire items were appropriately generated through multiple cycles of input from patients and clinicians. The most studied psychometric properties were internal consistency and convergent/divergent validity, with most instruments having Cronbach’s α >0.7 and acceptable correlation coefficients for convergent/divergent validity. Responsiveness, interpretability of the scale score, and validity testing in cross-cultural settings were either inadequately evaluated or missing. All instruments have a good readability level, an administration time less than 20 minutes, a time horizon of one week or less, and are multilingual. All questionnaires have been used in clinical trials for non-small cell lung cancer except CARES, CARES-SF and MQOL. CONCLUSIONS: There are several reliable and validated HRQoL instruments that are appropriate for use in clinical trials of NSCLC. In particular, the EORTC-QLQ30 and its lung cancer supplement, the LC13, LCSS, RSCL, FACT-L, and CARES have greater evidence of good psychometric properties. Further research is required to evaluate the cross-cultural performance, score interpretability and correlation with clinical outcomes of these instruments.

COST OF TREATMENT FOR SQUAMOUS CELL CARCINOMA OF THE HEAD AND NECK IN THE UNITED STATES
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BACKGROUND: Cancer of the head and neck is the 11th most common cancer in the US, however, there are no published, comprehensive studies examining the costs associated with the treatment of head and neck cancer in the United States. The objective of this research was to design a model to estimate the cost of treatment for squamous cell carcinoma of the head and neck (SCCHN). METHODS: A decision analytic model was designed to project the outcomes and costs associated with SCCHN. The model was stratified by site of disease, stage of presentation, treatment, and outcome. The most common therapeutic options for SCCHN were modeled: 1) surgery, 2) radiation therapy, 3) surgery and radiation therapy, 4) radiation therapy and chemotherapy, and 5) palliation. Base case data were obtained from the National Cancer Data Base, the published literature, a modified Delphi survey of experts, and an analysis of the Medicare Standard Analytic Files. RESULTS: Average per patient cost of care for SCCHN in the US was estimated to be $20,876. Higher costs resulted for patients that present with advanced cancers. The estimated cost of treating a patient with Stage IV lip SCC ($19,274) was four times that of Stage 0 lip SCC ($5,062). The site with the lowest cost of treatment was lip ($7,261) while the highest cost was associated with hypopharyngeal SCC ($28,584). The cost per patient for palliative care ranged from $2,052 for lip SCC (28% of total cost of care) to $7,172 for si-