OBJECTIVE: To examine the responsiveness to change of the Spanish version of the Juniper Mini Asthma Quality of Life Questionnaire (Mini-AQLQ). **METHODS:** 253 patients with mild to moderate uncontrolled asthma (patients with symptomatology and/or need for short-acting f''2-agonists) were included in the study (61% women, mean age 36 years). A full history and physical examination were performed and montelukast was added at the baseline visit. All subjects completed the Mini-AQLQ questionnaire twice: at recruitment and after two months. Differences in patient scores before and after the montelukast addition were analysed using paired t-test. Responsiveness was assessed by calculating the standardized effect size (SES). A within-subject change in score of 0.5 is defined as the minimal clinically important difference (MCID). **RESULTS:** The Mini-AQLQ was responsive to changes over a two-month period. All Mini-AQLQ global and domain scores significantly improved after montelukast addition (p < 0.01 for all comparisons). Mini-AQLQ score changes were significantly different for patients who improved and those that remained stable or deteriorated (p < 0.001). The global score effect size was 0.91, ranging from 0.5 to 1.0 for the domains. The percentage of patients with mild and moderate asthma who were considered to have experienced a MCID in global score was 57.5% and 71.4% respectively, with average baseline scores of 5.0 and 4.3 respectively. The domain that experienced the greatest number of patients experiencing a clinically important improvement was Symptoms, with 65% and 78% of patients with mild and moderate asthma respectively. **CONCLUSIONS:** The Spanish version of the Mini-AQLQ is suitable for use in longitudinal studies where it is appropriate to assess the impact of asthma on the quality of life of individual patients with mild to moderate asthma. A high proportion of patients experienced a clinically meaningful improvement in their Quality of Life after addition of montelukast to their asthma therapy.

CANCER

ECONOMIC IMPACT OF ADOPTING PEMETREXED PLUS CISPLATIN FOR MALIGNANT PLEURAL MESOTHELIOMA INTO SCOTTISH CLINICAL PRACTICE

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OBJECTIVE: To undertake cost-effectiveness evaluation of pemetrexed/cisplatin (pem/cis) compared to cisplatin (cis) for patients with advanced malignant pleural mesothelioma (MPM) in Scotland. **METHOD:** The efficacy of pem/cis versus cis was evaluated in the first randomised phase III trial in patients with unresectable MPM (Vogelzang 2003). Emergent data early in the trial led to patients being fully supplemented with folic acid and vitamin B12. Survival benefit was assessed in fully vitamin-supplemented patients with advanced disease [FS (stage III/IV)]. A cost/life-year saved (LYS) analysis of FS (stage III/IV) cohort using the median survival gain from the clinical trial was undertaken. This cohort was chosen because it represented the most realistic use of pemetrexed in Scottish clinical practice: most MPM patients in Scotland have advanced disease at presentation (Aziz 2002) and vitamin supplementation is mandatory with pemetrexed treatment (ALIMTA SPC). Specific unit costs were applied to drug acquisition, administration, supportive care medication, hospitalisations for serious adverse events and post-study chemotherapy, with incidence derived directly from the clinical trial. A discount rate of 3.5% per annum was applied to all outcomes. **RESULTS:** The survival of pem/cis over cisplatin in this cohort was 13.2 versus 8.4 months (p = 0.003; HR 0.63 [95%CI 0.46–0.86]). The incremental per patient cost for pem/cis compared to cis was £8196. The incremental cost/LYS for this cohort is £20,844. The robustness of the model was tested using one-way sensitivity analyses on key variables affecting both cost and outcomes estimates in the cost-effectiveness model. Little variation in the incremental cost/LYS was found with the variables tested for the FS with advanced disease patients (£17,500–£25,000). **CONCLUSIONS:** The trial demonstrated clear survival gain for the cohort of fully supplemented pem/cis patients with advanced disease. This analysis demonstrates that the combination may be considered a cost-effective treatment for patients with advanced MPM.

LEAD TIME IN THE EVALUATION OF HISTORICAL SURVIVAL IMPROVEMENTS IN THE TREATMENT OF ADVANCED NON-SMALL CELL LUNG CANCER

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OBJECTIVES: Historical evaluations of patients in clinical trials suggest that patients with advanced nonsmall cell lung cancer (NSCLC) treated with chemotherapy can expect a two-week improvement of median survival. We postulated that, with the publication of randomized trials showing survival improvements, this apparent gain might be attributable to lead time effects; that is, patients being treated earlier in the natural history of their disease. **METHODS:** Patients with Stage IIIb and IV nonsmall lung cancer were identified from the SEER-Medicare database, and population-based cancer registry linked to Medicare claims. Survival for consecutive cohorts diagnosed between 1994 and 1999 was analyzed to determine differences from time of diagnosis to time of treatment and for overall time from diagnosis to death. **RESULTS:** During this period 11,995 patients were diagnosed with stages IIIB and IV NSCLC. The mean age was 75 years, 57% were males and distribution by race was: 82.4% white, 9.4% African Americans, 3.2% Asian, 1.2% Hispanic, and 3.7% others. 30% were treated with chemotherapy. The mean time to chemotherapy initiation in 1994 was 1.63 months while in 1999 was 1.34 (p = 0.0004). This change represents a difference in treatment initiation of 8.7 days, or almost 62% of the survival benefit observed in the historical clinical trial evaluation covering 25 years. **CONCLUSIONS:** Over time there has been a trend towards earlier initiation of chemotherapy following diagnosis in advanced NSCLC. If the date from chemotherapy initiation is used as a starting point for survival analyses, as is frequently the case, researchers might erroneously conclude that survival is improving due to treatment, when in fact much of the apparent gains are simply due to patients receiving treatment earlier in the history of their disease.

POPULATION-BASED BUDGET IMPACT MODEL OF APREPITANT (EMEND) IN HIGHLY EMETOGENIC CISPLATINE-BASED CHEMOTHERAPY

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OBJECTIVES: To evaluate the economic impact of the introduction in the French market in 2003 of the new agent Aprepitant for the prevention of acute and delayed nausea and vomiting associated with Highly Emetogenic cisplatine-based cancer

Chemotherapy. **METHODS:** An analysis of the IMS Health ONCO Combined, LMPH, EHPP, GERS databases allowed identifying the anti-emetic schemes used in this indication in 2002, to draw up the market trend in ambulatory care and in hospital, and to determine the cost of corresponding consumption. A budget impact model was built over 4 years with several scenarii. The results are reported for 10,000 HEC cycles with a reduction in the use of the cisplatin of 5% per year, a 10%, 15%, 20%, 25% penetration rate of aprepitant, and a substitution rate in the delayed phase increasing from 30% to 90% over the period. **RESULTS:** The market share of 5-HT3 receptor antagonists was equal to 76% of the HEC market in 2002. In ambulatory care, the average cost of setrons in acute phase d1 and both in acute and delayed phases amounts respectively €26.90 and €111.25 per chemotherapy cycle. In hospital the corresponding figures are €33.02 and €147.50. The antiemetic treatment cost without aprepitant rises to €774,000 the first year and to €664,000 the fourth year. The net budget impact due to the introduction of aprepitant is €46,000 the first year and €41,000 the fourth year, i.e. less than 6% each year. In ambulatory care, this differential is €23,000 the first year and becomes nearly null cost over the four years. **CONCLUSION:** The overcost generated by the use of aprepitant is small for the French sickness funds compared to the overall antiemetic treatment cost.

COST OF CARE AND ECONOMIC IMPACT OF CETUXIMAB IN THE TREATMENT OF METASTATIC COLORECTAL CANCER IN SPAIN

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OBJECTIVES: The aim of this study was to estimate costs of care associated with metastatic colorectal cancer (MCCR) in current clinical practice and the potential impact on the Spanish health care budget of cetuximab prescription to patients with MCCR. **METHODS:** In order to describe treatment patterns and to analyse costs of MCCR, a cost of care treatment model was constructed. The economic impact of cetuximab was estimated by means of a treatment model for third-line use of the cetuximab combination after second-line irinotecan failure. Treatment patterns were obtained from questionnaires filled out by 14 Spanish hospitals and from an advisory board of 5 clinical experts. Treatment algorithms were constructed by using Tree Age Data Pro software. In order to estimate the unit costs, Diagnostic Related Groups were used for inpatient services, while outpatient services were calculated on daily based rates. Unit costs were obtained from national databases (€2004). The treatment costs were calculated from the perspective of the Spanish National Health System. The incidence of MCCR was obtained from literature review. **RESULTS:** For a population of 10,350 patients with MCCR in Spain, the total cost (pharmacological and medical costs) was estimated in €151 million. In that scenario, the cost of care of patients at third-line therapy that had failed to irinotecan therapy amounted €1.5 million. With the introduction of cetuximab after second-line irinotecan failure, a maximum of 193 patients were estimated to be eligible for the new drug. In this scenario, the total cost of the third-line therapy would come to €4.7 million. **CONCLUSIONS:** Cetuximab in combination with irinotecan is the only third-line therapy indicated in MCCR after irinotecan failure. If the eligible patients in third-line therapy received cetuximab and irinotecan instead of current clinical practice, the economic impact of substitution would amount €3.2 million.

THE COST OF SECOND-LINE TREATMENT OF OVARIAN CANCER IN POLISH SETTINGS

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OBJECTIVES: To evaluate direct treatment cost associated with pegylated liposomal doxorubicin hydrochloride (PLD) and topotecan used as second line therapies for ovarian cancer in Poland. **METHODS:** The literature review showed topotecan and PLD have similar efficacy in platinum-refractory or platinum resistant advanced ovarian cancer but different adverse events profile. The cost-minimization analysis was performed from the payer's perspective. Only direct medical costs (i.e. drug acquisition costs, drug administration costs and managing adverse events costs) were included. Based on epidemiological data budgetary impact of PLD treatment in Poland was estimated. **RESULTS:** The acquisition and drug administration costs were estimated at €12,448 and €6935 for PLD and topotecan, while cost of managing adverse events at €134 and €1234 for PLD and topotekan, respectively. The total cost per patient summed up to €12,882 for PLD and €8169 for topotecan. 38% reduction in acquisition cost of PLD would balance topotecan associated costs. Epidemiological data indicated 985 platinum-resistant or platinum-refractory ovarian cancer patients in Poland were eligible annually for treatment with PLD, thus additional cost could be estimated at €4.64 million. **CONCLUSIONS:** PLD represents attractive treatment strategy in second line therapy of platinum-resistant or platinum-refractory ovarian cancer, although acquisition cost reduction is necessary were compared to topotecan in Polish settings.

POPULATION-BASED BUDGET IMPACT MODEL OF APREPITANT (EMEND) IN MODERATELY EMETOGENIC CHEMOTHERAPY (MEC)

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The clinical study phase III 071 has showed the new antiemetic Aprepitant in association with a standard therapy (corticosteroid plus a 5-HT3 receptor antagonist) increases significantly the complete response (no vomiting and no rescue treatment) by more than 10 points compared to the standard therapy used in MEC. **OBJECTIVES:** To evaluate the budget impact implied by the introduction of this new antiemetic on the French sickness funds. **METHODS:** The MEC were defined according to the recommendations of the Multinational Association of Supportive Care in Cancer (2004). A sample of patients was extracted from the ONCO IMS 2004 database. The inclusion criteria used were: to receive a MEC in association with an antiemetic one containing a corticosteroid and a 5-HT3 receptor antagonist and to have this treatment during the acute and delayed periods. Prices of the antiemetic treatments were taken from the GERS 2004 database. A budget impact model was implemented over a period of four years, based on a stable population and on different penetration and substitution rates of Aprepitant. **RESULTS:** The results are reported for 10,000 MEC cycles associated to the standard therapy. The penetration and substitution rates of Aprepitant increase over the period from 10% to 25% and from 70% to 95%, respectively. In 2004, the treatment cost is €466,000. The introduction of Aprepitant increases the cost of the acute phase but decreases it in the delayed one. In the ambu-