The burden of multiple myeloma: assessment on occurrence, outcomes and costs using a retrospective longitudinal study based on administrative claims database.

**OBJECTIVES:** Multiple myeloma (MM) is a malignancy of plasma cells that results in an overproduction of light and heavy chain monoclonal immunoglobulins. Multiple myeloma imposes a significant economic and humanistic burden on patients and society. The present study is aimed to assess the burden of multiple myeloma in epidemiologic and economic terms. METHODS: A retrospective, naturalistic, longitudinal database study on the occurrence, outcomes and cost of multiple myeloma using an administrative database was performed. We selected residents of a North-Eastern Region of Italy, who had the multiple myeloma first hospital admission during the period 2001-2005, and we followed them until death, December 31, 2006, death or transfers. Direct medical costs were quantified in the perspective of the Regional Health Service. RESULTS: Out of a population if 1.2 million inhabitants, we enrolled 517 patients (52% female) leading to a crude incidence of 8.6/100,000 person-years. During the period of observation, 364 (70.4%) subjects died. Total health care costs per patient over the maximum of follow-up were €78,020 for the subjects younger than 70 years old and €23,096 in older group. CONCLUSIONS: The overall cost of MM is substantial, particularly in the first year after diagnosis and for hospital care. The natural history of the disease requires a great absorption of resources in the early phases after diagnosis and in the late stages of the disease. Multiple myeloma imposes a significant epidemiologic and economic burden to the healthcare- system and society.

A descriptive analysis of the association between breast cancer risk, bone mineral density and fractures in post-menopausal women in the Canadian Multicentre Osteoporosis Study.

**OBJECTIVES:** To explore potential correlations among risk factors for breast cancer, bone mineral density (BMD) and fractures in post-menopausal women (PMW). METHODS: A cohort of PMW aged 50–83 without breast cancer history (BC) was obtained from Canadian Multicentre Osteoporosis Study (CMOS). Bone density (D) and fracture (F) baseline cross-tabulation was performed for baseline BMD by incident BC. RESULTS: Gail score quartiles for 4,770 PMW were: Q1 < 1.329; Q2 = 1.381; Q3 = 1.968; Q4 > 1.968; mean = 1.77. PMW with family history of cancer (H), 76% had Gail scores in the 3rd (17%) and 4th (56%) quartiles. Older individuals had higher Gail scores, as proportions aged 50–59, 60–69, and 70+ within Q3 and Q4 were 8.5% & 11.7%; 30.3% & 22.4%; and 43.3% & 29.4%, respectively. Nearly 4% (n = 184) had incident BC, and most cases were diagnosed in women with Gail score quartiles. CONCLUSIONS: The association between risk of breast cancer and fractures in PMW is uncertain. Additional analyses adjusting for multiple confounders in this population is needed to help improve our understanding of this complex relationship.

Implementation of clinical intervention reporting system for pharmacists.

**OBJECTIVES:** To evaluate pharmacy clinical interventions done in the children cancer hospital Egypt during the period from July 2007 to March 2009. METHODS: The clinical intervention reports were recorded into a database made by the department of pharmaceutical services. RESULTS: A total of 362 Pharmacy Clinical interventions were recorded (this number constitute only 40% of the daily interventions), 52(14.4%) were category A (which is incomplete prescription (missing: Generic name, strength, dose, duration...etc.)), 58(16%) were category B, which is irrational pre-scribing; 39(10.8%) were category C, which is Excessive quantities, Unnecessary medication Duplication of therapy; 152 (41.9%) were category D, which is inappropriate dosage/route/flow rate/duration of therapy, where from the 152 Intervention in category D 65% was Inappropriate dosage, 15% inappropriate flow rate and 20% inappropriate duration of treatment; 25 (6.9%) were category E Drug-drug interactions; 8(2.2%) were category F, which is Allergy to a prescribed medicine; 11(3%) were category G, which is Drug incompatibilities-Disease e.g. GFD-Food -Lab tests; 14(3.9%) were category H, which is Drug monitoring is needed; 1 Intervention was category I, which is Dose adjustment is needed due to renal insufficiency and 2 were category J which is Dose adjustment is needed due to hepatic insufficiency. CONCLUSIONS: The 362 Pharmacy clinical interventions were all medical errors that were prevented by the pharmacy staff. The most interventions reported from category D regarding inappropriate dosage. The Pharmacy Clinical Intervention database will be used now on the floors, to encourage participation from the pharmacists and increased the reporting.

Cancer – Cost Studies

Budget impact analysis of dasatinib in patients with imatinib-resistant chronic myeloid leukemia (CML) in Brazil.

**OBJECTIVES:** To evaluate the impact, on Brazilian Public Health Care System (SUS) budget, of reimbursing for dasatinib for newly diagnosed CML patients who become imatinib-resistant. The budget impact analysis is conducted for three consecutive years. METHODS: Due to the rapid evolution of the disease, a monthly-cycle Markov model incorporating clinical and epidemiological data was developed to determine the target population throughout the analysis time. The base case analysis for imatinib-resistant CML patients compared the costs of imatinib (600–800 mg/day), versus dasatinib (45–90 mg/day). Disease progression depended on the best treatment response rates taken from START clinical trials. Pharmaceutical costs were obtained according to the official price and standard government discounting procedures, but alternative costing scenarios were also evaluated. Data sources for the epidemiological and treatment regimen distribution were used to populate the Markov model. Analyses were performed using Visual RCT and Markov Tree software. RESULTS: The budget impact of dasatinib was estimated as €1,431. Within one year’s time, 481 CML patients are expected to become imatinib-resistant. In the base case, the net budget impact was a savings of about €1,900,000 in 2009 to savings around €4,000,000 in 2011, with a total savings of approximately €8,000,000 over the 3 years. CONCLUSIONS: The inclusion of dasatinib as 2nd line therapy for newly diagnosed CML patients who have become imatinib-resistant in Brazil would result in increasingly and significant savings, even after accounting for uncertainties of the model.

Budget impact analysis of oral chemotherapy: real-world data analysis from payers’ perspectives in Brazil.

**OBJECTIVES:** In Brazil, health insurance companies (HIC) must offer coverage for intravenous chemotherapy drugs (IVCD), but not for oral chemotherapy drugs (OCD). We aimed to evaluate the incremental costs and the budgetary impact of the incorporation of OCD using real world data. METHODS: We prospectively collected data during 2008, on chemotherapy use in 14 HIC, on a population of 2 million people from different regions in Brazil. First we calculated the costs of the IVCD actually used. After that, we identified which patients would have formal indication for OCD either as a substitutive treatment or in association with IVCD. Then, we calculated the costs associated with this intervention. Later, the budgetary impact of using OCD for eligible patients was totaled. Only drug acquisition costs were taken into account. We were conservative and assumed a “worst case scenario” (WCS) approach as the base case, therefore skewing results against OCD. RESULTS: During the one-year period, 1,328 patients that received intravenous chemotherapy also had formal indication to receive OCD. The cost of the treatment actually done was US$19,630,000. If OCD were also used, the incremental cost would be an additional US$3,000,000. The relative incremental cost associated with OCD is therefore US$2.75 per capita per year or US$0.23 per capita per month, in a WCS. CONCLUSIONS: The budgetary impact linked with the adoption of OCD is of US$0.23 per capita per month, in Brazil, according to this real world data analysis.
during 2008. Appeals were evaluated according to literature sent and justifications. The budgetary impact was measured. RESULTS: A total of 960 chemotherapy bills from this HP were evaluated totaling US$1,277,181.12. There was at least one point of recommended coverage denial in 471 (49%) either of materials, drugs or the entire procedure. Cost was US$157,945.77. Denial was based on the best available evidence for each treatment. There were 100 appeals (US$47,889.11) following those denials, but 75% or more does not evidence was not reversed. We observed that contestations were more frequent for high cost drugs like Trastuzumab, Gemzar or Rituximab. The most frequent complaints was patient weight variation leading to the use of extra vials of these drugs, not previously approved. Interestingly, no such request was made for low-cost drugs. However, none of these variations resulted in dose increase larger than 5%, not justifying the waste of nearly all the drug in the vial. In none of these appeals was an ICAR applied. The ICAR was not used, which the coverage was denied based of incorrect form fillings or lack of any documentation. CONCLUSIONS: One in four denial appeals was reversed due to bureaucratic paper work. None of the other appeals was accompanied by supportive literature. Appeals are more frequent when high cost drugs are used in the chemotherapy.

EXPECTED ECONOMIC BURDEN OF TREATING ADVANCED SOFT TISSUE SARCOMAS WITH TRABECTEDIN IN RUSSIA

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OBJECTIVES: To determine the expected annual economic burden (EEB) of treating advanced soft tissue sarcomas (STS) with trabectedin in Russia. METHODS: EEB of treating advanced STS with trabectedin was calculated in a model in comparison with EEB of bevacizumab for metastatic colorectal cancer (CRC) and sorafenib for advanced renal cancer (RC). All studies used are for advanced cancer and have been conducted in Russia. The expected increase of usage for trabectedin was based on the following assumptions: 1) trabectedin is given to patients with a new case of STS revealed at advanced stage and resistant to first-line therapy; 2) according to federal standards of care, bevacizumab is given to 80% of patients with a medical indication for (CRC) and 3) sorafenib to 30% of patients with new case of metastatic RC. Number of new cases of advanced cancer was taken from the annual report about cancer morbidity and mortality in Russia. Dosing regimen of drugs were taken from clinical studies. Prices of bevacizumab and sorafenib were taken from RMBC database, price of trabectedin was proposed by the manufacturer.

RESULTS: EEB of trabectedin was estimated to be 2.3 billion rubles (a. US$67.4 million) per year. EEB of bevacizumab for metastatic CRC was 16.0–21.3 billion rubles (a. US$533.1–US$710.8 million). EEB of sorafenib for metastatic RC was 5.8 billion rubles (US$194.5 million) per year. CONCLUSIONS: EEB of trabectedin is less than of some other drugs for advanced cancer with comparable efficacy that have already been recommended for use in a health care system. Bevacizumab is included into federal standards of care, sorafenib is included into Essential Drug List, that means that these drugs should be available to patients. Therefore trabectedin looks affordable for the system.

NUMBER NEEDED TO TREAT (NNT) TO AVOID ONE GASTROINTESTINAL STROMAL TUMOUR (GIST) RECURRENTENCE IN BRAZIL. COST COMPARISON AND BUDGET IMPACT ANALYSIS OF ADJUVANT TREATMENT WITH IMatinib

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OBJECTIVES: To calculate the NNT to avoid a recurrence of GIST after resection, to compare the cost of adjuvant treatment with imatinib (IM) with the cost of recurrence, and to estimate a budget impact from the Brazilian Public Health Care System (SUS) perspective.

METHODS: Available relative risk reduction at 1 year from the Z9001 clinical trial and historical rate of recurrence for no adjuvant treatment were applied to estimate absolute risk reduction and NNT. Adjuvant treatment effect was extrapolated to 3-year period as ongoing trials are investigating longer treatment duration (SG XVIII). A 5-year time horizon was set for cost comparison and Budget Impact Analysis (BIA). Incremental Cost to Avoid Recurrence (ICAR) was defined as the difference between the cost of adjuvant treatment (IM, monitoring) and the cost of recurrence (IM, surgery, monitoring, best supportive care). ICAR was applied to adjuvant GIST incidence for BIA. Epidemiological data (incidence, proportion of resectables); health access, diagnosis and expected adjuvant treatment rates were obtained from literature. Resource utilization and cost data came from official guideline and administrative databases, literature, and expert opinion. Costs are reported in 2007 Euros. A 5% discount rate was applied. Univariate sensitivity analysis was performed. RESULTS: The NNT to avoid a recurrence was estimated at 2.1 based on an extrapolated GST recurrence risk profile in Brazil. Cost of adjuvant treatment was €50,298 and the cost of a recurrence €61,998. Annual ICAR was €8,725. The annual impact on the Ministry of Health budget was 0.01%, which included impact on infrastructure (e.g. monitoring cost of IM, surgical charge) were sensitive to the recurrence rate and adjuvant treatment duration. CONCLUSIONS: Considering that imatinib is already reimbursed by SUS for metastatic/unresectable GIST, adjuvant therapy for primary GIST represents good value for money for the prevention of recurrence, and an annual budget impact of 0.01%.

COST-EFFECTIVENESS AND BUDGET IMPACT ANALYSIS OF USING TEMSIROLIMUS COMPARED TO INTERFERON ALPHA IN METASTATIC RENAL CELL CARCINOMA

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OBJECTIVES: The purpose of the study was to evaluate the cost effectiveness and budget impact in patient weight impact leading to the use of extra vials of these drugs, not previously approved. Interestingly, no such request was made for low-cost drugs. However, none of these variations resulted in dose increase larger than 5%, not justifying the waste of nearly all the drug in the vial. In none of these appeals was an ICAR applied. The ICAR was not used, which the coverage was denied based of incorrect form fillings or lack of any documentation. CONCLUSIONS: One in four denial appeals was reversed due to bureaucratic paper work. None of the other appeals was accompanied by supportive literature. Appeals are more frequent when high cost drugs are used in the chemotherapy.

NEW TREATMENT OPTIONS FOR ADVANCED GASTROINTESTINAL STROMAL TUMOURS: COMPARATIVE STUDY OF BEVACIZUMAB vs SUNITINIB IN SPAIN

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OBJECTIVES: To perform a cost analysis comparing the management of adverse events (AEs) and their associated cost in current clinical practice of bevacizumab (BEV) + interferon alpha-2a (IFN) versus sunitinib (SUN) in patients with metastatic renal cell carcinoma (mRCC) in Spain. METHODS: A decision analytic model was developed to compare the costs derived from the management of grade 3/4 AEs in patients with mRCC, using data from published studies. RESULTS: The model yielded ICER $8944 per progression free life months gained. Cost effectiveness was conducted using a Markov state-transition model in TreeAge. Time dependent transition probabilities were calculated using multivariate Kaplan Meier estimators based on clinical trial data. An Excel-based budget impact model was developed to compare two scenarios, one for the interferon scenario and one for the temsirolimus scenario. Inputs were obtained from SEER registry, clinical trial, and US census bureau. Sensitivity analyses were performed. RESULTS: The model yielded ICER $8944 per progression free life months gained. For a hypothetical managed care plan with 500,000 members, the Budget Impact model estimated 33 patients with mRCC. A 75% (n = 24) eligible patients would be treated with IFN. Assuming that temsirolimus was available to 12% of eligible patients the expected 30 months cost would be US $18215.7 per patient compared with $13,557.96 had all patients been treated with IFN alone. CONCLUSIONS: Tensirolimus was found not to be dominantly cost effective compared to interferon alpha-2A. This finding is indicative of two challenges: 1) temsirolimus needs to be available at a reduced cost; 2) its threshold for cost-effectiveness needs to be adjusted according to relative clinical efficacy. The budgetary impact of adding temsirolimus to health plan was estimated to be minimal. While its current availability allows new treatment options, temsirolimus may be too expensive to use in some managed care plans.