

twice that of ZOL in the US. NNT represents the number of patients that need to be treated with a new therapy in order to avoid one additional event, and is a useful approach to assess the relevance of therapies in the real life clinical setting. In this statistical analysis, the NNT approach was used to assess the incremental benefit of Dmab over ZOL for the prevention of SREs in patients with other solid tumours and MM.

**Methods:** The pivotal phase III randomized data for Dmab vs. ZOL was reviewed (US PI, 2010). As an alternative to ZOL, the NNT with Dmab to avoid any SRE at 24 months was determined. NNT by type of SRE was also estimated. These consisted of pathologic fractures, radiation to bone, spinal cord compressions and surgery to bone. The calculated NNT represents the incremental benefit provided by Dmab above and beyond Zometa therapy.

**Results:** To avoid a single SRE at 24 months of continuous therapy with Dmab, approximately 21 patients would need to be treated. To avoid a single fracture, radiation to bone and surgery to bone, 56, 36 and 167 patients need to be treated with Dmab over a 24 month period. In addition, Dmab was unable to offer any incremental benefit over ZOL in terms of avoiding spinal cord compressions.

**Conclusion:** The NNT approach is a simple and effective method to express the findings in a clinically meaningful way. In this analysis, the incremental benefit of Dmab would only be realized when a minimum of 21 patients are treated for 24 months in order to prevent 1 additional SRE. For those SREs (i.e. surgery to bone and spinal cord compression) that are typically considered the most clinically and economically severe events, 167 patients would need continuous treatment with Dmab to avoid one surgery to bone event, while Dmab offered no incremental benefit in terms of avoiding spinal cord compressions. These marginal incremental benefits need to be considered alongside the high cost of Dmab.

3604

POSTER

#### First-line Bevacizumab Plus Taxane-based Chemotherapy for Metastatic Breast Cancer (mBC): Cost Minimisation Analysis

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**Background:** Bazan *et al.* assessed first-line bevacizumab plus taxane-based chemotherapy for metastatic breast cancer (mBC) and showed no difference of Progression Free Survival (PFS) between two treatments (bevacizumab plus docetaxel – BD versus bevacizumab plus paclitaxel – BP), with median values of 10 months [8–13] (HR = 1.32 [0.81–2.17],  $p=0.26$ ) (Abstract submitted ECCC 2011 by Bazan *et al.*). In the context of rational decision-making in health care, the purpose of this study is to carry out a cost minimisation analysis including a comparison of the costs to the French Public Health Insurance arising from first-line treatment by BD versus BP for patients with mBC.

**Material and Method:** Of 86 patients included in the Bazan *et al.* study and for which effectiveness data were analyzed, 7 patients are always treated and are thus excluded from economic analysis. It took into account costs related to drug acquisition, hospital care for chemotherapy administration and for toxicity and transport. Hospital resources cost was based on the French public Diagnosis-Related Group database. Drug acquisition costs (bevacizumab, docetaxel, paclitaxel) and transport were respectively drawn from French official sources (reference 2011). As our study took place over a limited period of time, no discounting was performed. Costs are expressed in euros (€). To gain insight into the uncertainty around the total cost difference, standard non-parametric bootstrap stimulations were conducted (10,000 replications).

**Results:** The number of chemotherapy administration was significantly higher for patients treated by BP compared patients treated by BD. No difference was observed in terms of hospitalization for toxicity. First-line BP chemotherapy for mBC was associated with a mean total cost higher than first-line BD chemotherapy, respectively  $49,299 \pm 33,026$  versus  $54,710 \pm 31,423$ , i.e. an differential cost of 5,411€. The chemotherapy cost represents respectively 84% and 80% of the total cost. Sensitivity analysis confirmed robustness of results, with a saving cost of 5,359€ per patient treated with BD ( $p < 10^{-4}$ ).

**Conclusion:** In lack of difference of PFS between two treatments (BD versus BP), our cost minimisation analysis tends to show a significant cost decrease associated with first-line treatment by BP for patients with mBC, candidate for one of these treatments.

3605

POSTER

#### Health Resource Utilization and Costs Associated With Gastric Cancer – Results From a US Claims Database

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**Background:** While gastric cancer (GC) is a worldwide problem, there is little information regarding its economic burden from a payer perspective. The objectives of this study were to estimate real-world costs associated with GC, specifically metastatic disease.

**Materials and Methods:** Retrospective analysis of direct costs and healthcare services use in GC patients and controls using IMS LifeLink™ Health Plan Claims (US) Database. Cases were  $\geq 18$  years of age and newly-diagnosed with GC in 2007–2009 (first GC diagnosis as index date). Cases were excluded if they had evidence of cancer in the 360 days prior to index or evidence of cancer other than gastric 4 weeks after index. Controls (individuals without GC) were matched 1:1 with cases (98.4%) on age, gender, region, health plan and payer type, and length of follow-up. Costs are reported as monthly means. Patients were classified as metastatic if they had a claim for a secondary malignant neoplasm (ICD-9-CM 197.x, 198.x) in post-index period.

**Results:** A total of 303 GC cases were identified and matched to a control. Mean age of the sample was 58 and 55% were male. Median follow-up was 364 days. Total mean monthly costs were significantly greater for cases (\$10,653 vs. \$571) as were hospitalizations, emergency room visits, physician office visits, laboratory and radiology procedures, and pharmacy services ( $p < 0.0001$ ). The most pronounced difference was for inpatient services with 75% of cases hospitalized during follow-up vs. 9% of controls ( $p < 0.0001$ ), resulting in a 35x greater cost for inpatient care (\$6,511 vs. \$182). When stratifying our overall GC sample, metastatic patients (N = 90, 30% of GC sample) incurred disproportionately higher costs on all utilization variables. Cost differences between metastatic and early stage patients were found for outpatient pharmacy services (\$1727 vs. \$293), inpatient services (\$10,282 vs. \$4918), and ancillary services (\$2560 vs. \$882). Overall, the mean monthly cost to treat a metastatic patient was more than 2x greater than the cost to treat an early stage patient (\$17,289 vs. \$7849).

**Conclusions:** The mean total monthly healthcare cost for newly diagnosed GC patients was 18 times higher than matched controls without GC. The largest difference was in inpatient costs, followed by drug and radiology costs. Interestingly, metastatic disease costs were more than double those for early stage GC patients, largely due to pharmacy, ancillary, and inpatient services. On a monthly per-patient basis, GC is associated with significant costs especially in metastatic patients.

3606

POSTER

#### Incidence of Costly Cancer Treatment in Two Health Care Services

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**Background:** The equitable access to medical treatment accordingly to individual needs is an important issue to discuss taking into account that resources are limited.

In this study we describe the incidence of costly cancer drugs with antitumour effect in a Social Healthcare Service with national coverage and 350000 beneficiaries and in a Private Medical Insurance Company with 500000 affiliates, from January 2010 to December 2010.

**Material and Methods:** Retrospective study. Source: clinical history and files from patients on anticancer treatment from January 2010 to December 2010.

**Results:** In the Social Healthcare Service, 7.22% of the total cancer patients (1281) received costly cancer treatment. The most used therapies were: Rituximab (31.5%), Bevacizumab (16.85%) Trastuzumab (16.85%). The most frequent cancers that received costly cancer drugs were haematological (32.5%), breast (22.5%), colorectal (13.5) and lung (11.2%).

In the private Medical Insurance sector, with over 500.000 affiliates, 0.86% received pharmacological treatment for solid tumours.

101176 pharmacological units were dispensed. From this, the Top 3 High Cost treatment dispensed by units were: Trastuzumab with 5.26% of units and 31.1% of the total cost; Bevacizumab with 4.3% of units and 12.8%

of the total cost and Cetuximab with 0.74% of units and 3.26% of the total cost.

**Conclusion:** The regulation in the use of costly drugs including expensive cancer treatment is an important issue in health insurance programs. Nowadays with many expensive emerging technologies, particularly therapies for cancer, there is a need for pharmacoeconomic studies. We need to generate a model of coverage analysis enhancing participation of all parts in order to warrant adequate access to these expensive treatments.

3607

POSTER

# **Review of Meta-analyses Evaluating Surrogate Endpoints for Overall Survival (OS) in Oncology**

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**Background:** OS is the gold standard in measuring treatment effect of new drug therapies for cancer. However, practical factors may preclude the collection of unconfounded OS data and, therefore, surrogate endpoints are often used instead. Meta-analyses have been widely used for validation of surrogate endpoints, specifically in oncology. This research reviewed published meta-analyses on the types of surrogate measures used in oncology and examined the extent of correlation between surrogate endpoints and OS for different cancer types.

**Methods:** A search was conducted in Oct 2010 to compile available published evidence in the English language for validation of disease progression-related endpoints as surrogates of OS based on meta-analyses. Extensive efforts were made to follow citations, and data was extracted by tumour type in metastatic disease.

**Results:** Published meta-analyses (N=26) were identified covering 6 advanced solid tumour types. Results that quantified the correlation between progression-free survival (PFS) and OS are shown in Table 1. In non-small cell lung cancer, 3 meta-analyses reported on response rate or time to progression but not PFS. One publication in head & neck cancer reported strong correlation between event-free survival and OS in multiple settings. One abstract in renal cell cancer presented a meta-analysis showing correlation (0.69) between effects on PFS and OS based on 21 trials.

Table 1. Supporting evidence for use of PFS as surrogate for OS

Tumour type	No. of meta-analyses	R <sup>2</sup> ind	R <sup>2</sup> trial	Surrogate threshold effect (STE) or prediction
Colorectal	4	0.23–0.67	0.52–0.98	STE (for PFS) = 0.86 HR PFS <0.77 predicts OS benefit
Ovarian	3	0.44–0.70	0.36–0.95	STE = 0.55
Breast	4	0.14–0.47	0.30–0.78	HR PFS = 0.7 predicts HR OS = 0.88
Prostate	2	0.09	0.22	Not reported

R<sup>2</sup><sub>ind</sub> measures relationship between endpoints by treatment arm; R<sup>2</sup><sub>treat</sub> measures relationship between treatment effects on endpoints by study; STE = minimum effect on the surrogate endpoint necessary to predict a nonzero effect on the target endpoint.

**Conclusions:** PFS is the most commonly used surrogate measure in studies of advanced solid tumours, and correlation with OS is reported for a limited number of cancer types. Given the increased use of crossover in trials and availability of second/third-line treatment options available to patients after progression, it will become increasingly more difficult to establish correlation between effects on PFS and OS in additional tumour types.

3608

POSTER

# **Castrate-Resistant Prostate Cancer – Clinical as Well as Economic Factors Should Influence Treatment Practice**

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**Background:** New payment strategies developed by payers as an alternative to fee-for-service have been designed to improve care coordination. These innovations occurred during the same time frame that several new treatment options were approved for castrate-resistant prostate cancer (CRPC) and are now included in treatment regimens for this stage of disease. This study reviewed new payment strategies and identified the most common pathways in practice to assess and evaluate resources used. Whether new payment strategies could affect treatment pathways in CRPC was also considered.

**Methods:** Through published literature, public records, and phone interviews with payer organizations with pilot payment programs in place, 11 innovative payment and delivery models from 1996–2010 were analyzed. In addition, by reviewing the CRPC literature and NCCN guidelines, and through a standardized questionnaire to oncology practices, common treatment pathways were identified. Financial resources associated with pathways were evaluated using Medicare reimbursement rates.

**Results:** Most pilot strategies bundled episodes of care and payment but only 5 models focused on oncology, none on prostate cancer (PCa); 1 pilot for early-stage PCa will begin this year. Ten alternative treatment pathways for CRPC were determined, including sequences of watchful waiting, hormonal therapy (luteinizing hormone-releasing hormone), antiandrogen withdrawal, ketoconazole, chemotherapy (docetaxel, cabazitaxel), and immunotherapy (sipuleucel-T). Costs of pathways varied widely depending on specific therapies utilized. Regimens that included mainly secondary hormonal therapy were least expensive, ≤\$25,000/patient, while those including newer treatment options were more costly, ranging up to ~\$140,000.

**Conclusions:** The unique nature of oncology practice may prove challenging to a system of payment strategies based on episodes of care because most cancer is treated by an interdisciplinary team in a variety of settings. In this analysis of CRPC payment models, cost varied substantially based on the treatment chosen, with the newest options being more expensive. If bundled episodes of care are to be used successfully in the CRPC population, clinical guidelines, patient health status, response to therapy, and potential for survival benefit primarily should be used to determine choice of therapeutic regimen so that access to the newest treatments with proven clinical outcomes is not limited.

3609

POSTER

# **The Multidisciplinary Approach in Advanced Prostate Cancer: a Critical Need Today**

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**Background:** Many new therapies, including cabazitaxel, sipuleucel-T, denosumab, zoledronic acid, and abiraterone, have been developed recently for advanced prostate cancer (PCa). Treatment with these agents may involve several clinical disciplines and so, it has been proposed within the current literature that the multidisciplinary approach (MDA) be adopted for optimal patient management in PCa. This approach is well known in certain oncology specialties, such as breast cancer, and has led to better outcomes. We investigated the quality and magnitude of the efficacy of the MDA in PCa treatment and whether advanced PCa is part of current MDA initiatives.

**Materials and Methods:** To examine evidence supporting the efficacy of the MDA in treatment of advanced PCa, the evidence-based PCa literature was searched for the past 5 years using the search terms MDA, care coordination, medical home, and patient management for PCa. Also, source references of appropriate articles found were evaluated. Additionally, through field-based searches using standardized search parameters, a sample of US PCa healthcare professionals with clinical practices purporting to implement the MDA were identified and interviewed.

**Results:** Of 270 search-identified articles and 559 from source references, 32 articles addressed the MDA in PCa. In general, identified publications lacked a uniform definition of MDA and methodologic variability was substantial. Most of the literature was descriptive and none of the articles presented clinical outcomes; few specifically discussed advanced PCa. Only 7 of the 14 MDA providers interviewed were part of a medical service offering true MDA; the other 7 retrospectively reviewed select cases via a tumour board. Notably, MDAs that the clinicians participated in focused on early localized disease and not on castrate-resistant disease, as this was viewed as noncontroversial with well-defined treatment regimens. There was no consensus as to the opportune time to refer advanced patients to medical oncology.

**Conclusions:** While the concept of the MDA in PCa is widely supported, MDA is poorly defined in the literature and rigorous studies of outcomes are nonexistent. Few centers have implemented an MDA, especially in the latter stages of disease. The wealth of new agents has made the need for the MDA critical in advanced PCa, as only a coordinated approach will enable best use of these agents and potential sequences to improve quality care.