vivors, specifically female survivors over 65 years had greater risk of work loss than general population. These findings should help working people concerned about employment after lung cancer.

CANCER – Health-Care Use and Policy Studies

PCN138

HEALTH-CARE COSTS ASSOCIATED WITH BREAST CANCER MANAGEMENT

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OBJECTIVES: To assess the outpatient direct costs related to early and metastatic breast cancer (BC) management in Campania, a Southern Italy region. **METHODS:** This is a retrospective cohort study based on clinical records from 457 general practitioners who managed an average of 630,000 inhabitants in Campania. Incident early BC cases from 2005 to 2007 were identified and costs related to outpatients management were calculated until evidence of local recurrence or metastases (BC Event), death, revocation or the end of the database (December 31, 2009). For those patients who developed a BC event, costs for their disease management were further analyzed from the time of the event until death, revocation, or the end of the database. Monthly cost per patient was expressed in Euros. **RESULTS:** A total of 1529 patients with early BC were identified in the database. Of these, 112 women developed a BC event during the study period. At a median follow-up of 34 months, adjusted monthly primary care cost per patient was €151.87 in the subset of women with early BC. For those who experienced a BC event, at 24 months of follow-up, adjusted monthly primary care cost per patient was almost doubled: €289.15 ($P < 0.0001$). Main causes for this cost difference were related to increased number of specialists'visits, diagnostic procedures, and laboratory test once a BC event developed. **CONCLUSIONS:** Outpatient's management in women with metastatic BC is twice more expansive compared to management of women with early BC. Reasons for this increase are mainly due to increased frequency of imaging and diagnostic procedures in the metastatic BC subset. However, our study underestimates the total costs for metastatic BC patients' management because hospitalization and chemoptherapy costs are not included in our analyses. Based on our data, secondary and tertiary prevention strategies must be significantly implemented in order to rationalize resource allocation.

PCN140

IMPROVING PATIENT ACCESS TO CANCER DRUGS IN INDIA: USING ECONOMIC MODELING TO ESTIMATE A DRUG COST BASED ON MEASURES OF SOCIETAL VALUE

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OBJECTIVES: Cancer patients from lower-income countries such as India often have limited access to modern medicines because of high costs. Using multiples of India's per capita GDP as the threshold for economic value as suggested by the World Health Organization (WHO), decision analysis modeling was used to estimate a monthly cost for a hypothetical new cancer drug that provides a 3-month survival benefit to patients with metastatic colorectal cancer (mCRC). **METHODS:** A decision model was developed to simulate progression-free and overall survival in mCRC patients receiving chemotherapy ± the new drug. Outcomes for cancer control and side effects were obtained from randomized trials evaluating 1st and 2nd line chemotherapy in mCRC. Costs for chemotherapy were obtained from both public and private hospitals in India. Utility estimates measured as quality-adjusted life-years (QALY) were determined from 24 oncology nurses using the Time Trade-Off technique. These data were then used to estimate the monthly cost of the new drug using a threshold of $9300 per QALY gained, which is three times the Indian per capita GDP, as recommended by the WHO. **RESULTS:** The base-case analysis suggested that a monthly cost of $U.S.98 would be considered cost-effective from the Indian public health-care perspective. If the drug were able to improve patient quality of life above the standard of care or survival from 3 to 6 months, the monthly drug cost could increase to $U.S.170 and $U.S.253 and offer the same value. **CONCLUSIONS:** The use of the WHO criteria for estimating a country-specific drug price based on economic value for a developing country is feasible. However, the challenge would be to identify an appropriate threshold that would provide a balance between what patients/governments can afford to pay and the commercial viability of the product in the reference country.

PCN141

TRANSPARENCY OF DRUG REIMBURSEMENT IN POLAND—ONCOLOGY

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OBJECTIVES: Increasing the level of transparency of decision-making process of reimbursement for drugs used in oncology by facilitating online access to public information and other information regarding the refund of cancer drugs in Poland compared to solutions used in the world. **METHODS:** The project will develop a comprehensive system to monitor the transparency of reimbursement decision-making process in Poland consisting of: Guidelines and Clinical and Reimbursement Recommendations Database (WiRKliR database) whose purpose is to collect documents from the Polish and selected countries of the clinical guidelines, registration, and decisions about the recommendations and decisions regarding reimbursement for cancer drugs and present information contained in them in a comprehensible and transparent. Reimbursement monitoring which aims to carry out continuous monitoring of the implementation of law and regulation in the field of oncology drug reimbursement and the acquisition of complementary information about the cancer drugs in the database WiRKliR. Reimbursement reports whose purpose is to discuss the issue of transparency of reimbursement through the analysis of procedures drawn up and applied by public authorities in dealing with citizens, with special emphasis on patients and pharmaceutical companies in the reimbursement decision-making process and to present the results of the various stages of our work. **RESULTS:** The most important results of the project include: increased transparency of institutions involved in the drug reimbursement decision-making process, the democratization of medical information, provide decision-makers Polish health-care system expertise, to increase patient awareness about their rights and proposals for corrective actions (conclusions and recommendations) for public administration in the area of the refund. **CONCLUSIONS:** A comprehensive monitoring system for civil funding allocation process in the health-care system to counteract the imbalance of information.

PCN142

WHAT IS THE CURRENT R&D LANDSCAPE FOR METASTATIC BREAST CANCER? AN INVESTIGATION INTO RECENT CLINICAL TRIAL ACTIVITY

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OBJECTIVES: A number of systemic therapies are available for the treatment of metastatic breast cancer (MBC)—including hormonal therapies, chemotherapeutic agents, and biologics—but long-term prognosis remains poor. There is a need for new treatments that improve survival and are effective in a greater proportion of patients. This research evaluates the recent clinical trial activity directed toward the treatment of MBC. **METHODS:** MBC trials were identified through a systematic search of the records within http://www.clinicaltrials.gov, using the search term "metastatic breast cancer OR stage IV breast cancer OR advanced breast cancer." Trials with a start date from January 2008 onward were included and categorized by nature of intervention (new investigational agent, drug launched for indications other than breast cancer, or approved breast cancer product); all trials that did not include a pharmaceutical (biological or drug) were for an unsuitable indication, or that were suspended, terminated, or withdrawn were excluded. The remaining trials were evaluated for a number of variables, including phase of development and product type. The overall number of pharmaceuticals under investigation was also explored. **RESULTS:** The original search term identified 2014 trials, 365 of which met the inclusion criteria. a large proportion of these trials (41%) were evaluating products already approved for the treatment of breast cancer. Of the remaining trials, 68% were investigating new agents; the remainders were evaluating a product launched for an indication other than breast cancer. There were a total of 116 new products under investigation, although these were mainly at an early stage of development with just 8% of trials at Phase III/IV. **CONCLUSIONS:** MBC is a key area of research, with a large number of products in development. However, since the majority of clinical trials are at an early stage, it will be some years before these products impact patient treatment.

PCN143

PRIMARY PREVENTION AS EXPANDED INDICATION TO MITIGATE COMPETITION: A CASE STUDY

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OBJECTIVES: While there are several instances of products gaining expanded indications from secondary treatment to primary treatment/prevention, in some cases, expanded indications appear to buffer the drug utilization from competitors. However, the extent to which the later expanded indications impact the utilization of the product across the lifecycle, including following loss of exclusivity, is not well understood. The objective was to examine the prescribing volume of a drug throughout its lifecycle in conjunction with the uptake of a novel class of drugs launched for similar indications to examine the impact of the expanded primary treatment/prevention indications on competition. **METHODS:** Tamoxifen and the aromatase inhibitors letrozole and anastrozole were selected as case products. All three drugs are FDA indicated for the treatment of advanced breast cancer, yet tamoxifen is the only drug of the group FDA indicated for the primary prevention of breast cancer. From January 1992 to April 2010, the volume of prescriptions (TRx) was collected monthly using SDI's VONA database and grouped according to class sales by active molecule. **RESULTS:** Generic sales of tamoxifen maintained a high level after the 1998 approval for the primary prevention indication of "reduction in breast cancer incidence in high-risk women" despite competition within active breast cancer treatment indications from the aromatase inhibitors. While the aromatase inhibitors launched in the mid-1990s, their utilization did not begin to encroach on total tamoxifen prescriptions until the expiration of exclusivity for tamoxifen's prevention indication in 2003. **CONCLUSIONS:** This preliminary analysis shows that the strategy of obtaining a later primary prevention indication may help maintain utilization of a compound across the lifecycle. The hypothesis that a prevention indication expansion could mitigate competition should be further examined among products where primary prevention and primary treatment indications have distinctly different dosages and/or branding and where the additional indication is protected by extended exclusivity.