of the time to symptom progression (TSP), time to deterioration (TDD) in trial outcome index (TOI), and time to deterioration (TDD) in QoL. An exploratory analy-
sis based on the time to analgesia and appearance of key symptoms (pain, cough, and dyspnea) was also performed. RESULTS: FACT-L completion rates were above 90% at all study visits. At baseline, QoL measures were similar between the two treatment groups. Maintenance therapy with erlotinib did not negatively impact on QoL, compared with placebo, as illustrated by comparable TSP (HR = 0.91 [0.74–
1.12], n = 785), TTD in TOI (HR = 1.06 [0.87–1.31], n = 781), or TTD in QoL (HR = 0.96 [0.79–1.16], n = 776). Exploratory analysis of NSCLC-related symptomatology showed that time to pain and time to analgesic use were significantly delayed in patients receiving erlotinib compared with placebo (HR = 0.61 [0.42–0.88]; P = 0.0080 and HR = 0.66 [0.46–0.94]; P = 0.0199, respectively). There was also a non-significant trend toward delayed time to cough and time to dyspnea (HR = 0.77 [0.49–1.21] and HR = 0.75 [0.48–1.17], respectively). CONCLUSIONS: Erlotinib maintenance therapy significantly extends progression-free survival, without compris-
ing patient QoL and with some improvement in symptoms.

**EORTC, Brussels, Belgium; 2Medical University of Graz, Graz, Austria; 3University Hospital Thailand, Lebanon, where body image and death are taboos). All together, there were received comments about offensiveness or disturbing nature of questions about body
In the most recent 15 translations of QLQ-MY20, pilot-tested on 85 patients in 16 new translation or to provide no change (e.g., because the only solution would be to
In the Translation Manual, one step is pilot-testing, involving 10 to 15 patients who
In the TRANSLATION PROCEDURE described
OBJECTIVES: The aim was to review the impact of this study to compare the impact of two treatment modalities, erlotinib or placebo, on quality of life of patients with non-small cell lung cancer (NSCLC).

**EPICLIN-LUNG STUDY: NON-SMALL-CELL LUNG CANCER (NSCLC)
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MANAGEMENT
HEALTH-CARE COSTS ASSOCIATED WITH BREAST CANCER

Malorni L2, De Placido S2, Arpino G2
North-West University, Potchefstroom, South Africa; 3PharmARC Analytic Solutions, CAMMARAOTA S1, CITARELLA A1, MENDITTO E1, PUTIGNANO D1, Riegler S1, De LUCA L1

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 outpatient 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 costs per patient were 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 developed 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 specialist visits, diagnostic procedures, and laboratory test once a BC event developed. CONCLUSIONS: Outpatient management of women with metastatic BC is twice more expensive 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 chemotherapy 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.

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

PCN142

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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 formulation and where the additional indication is protected by extended exclusivity.

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

PCN140

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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 breast cancer (mBC). METHODS: A decision model was developed to simulate progression-free and overall survival in mBC 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 mBC. 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 $US 95.98 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 $US 170 and $US 253 and offer the same value.

TRANSPARENT AND REIMBURSEMENT IN POLAND—ONCOLOGY

PCN141

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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 publicly available 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 Reimbursement Recommenda
dations Database (WiRKS&R 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 on 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 WiRKS&R. 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 result 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 expertize, to increase patient awareness about their rights and proposals for corrective actions (conclusions and recommendations) for public administration in the area of refund. CONCLUSIONS: A comprehensive monitoring system for civil funding allocation process in the health-care system to counteract the imbalance of information.

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

PCN138

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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 outpatient 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 costs per patient were 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 developed 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 specialist visits, diagnostic procedures, and laboratory test once a BC event developed. CONCLUSIONS: Outpatient management of women with metastatic BC is twice more expensive 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 chemotherapy 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.

TO ASSESS THE OUTPATIENT DIRECT COSTS RELATED TO EARLY AND METASTATIC BREAST CANCER (BC) MANAGEMENT IN CAMPAOIA, A SOUTHERN ITALY REGION.

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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 outpatient 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 costs per patient were 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 developed 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 specialist visits, diagnostic procedures, and laboratory test once a BC event developed. CONCLUSIONS: Outpatient management of women with metastatic BC is twice more expensive 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 chemotherapy 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.