The pan-Canadian Oncology Drug Review (pCODR) was established in 2010 to provide provinces and territories with recommendations on reimbursement for cancer drugs. OBJECTIVES: The objective of this study was to analyze the recommendations made by pCODR in its first year of operation and identify trends. **METHODS:** Clinical and economic guidance reports and recommendations, publically accessible at <u>www.pcodr.ca</u> were reviewed. RESULTS: Since pCODR began accepting submissions in 2011, ten of twenty applications have received recommendations. Of the seven positive recommendations, one suggested a more limited patient population than the one requested (Votrient - metastatic renal cell carcinoma). In six cases (Afinitor, Halaven, Jakavi, Sutent, Yervoy, Zelboraf), positive recommendations for the requested population were made, conditional on cost-effectiveness being improved to an "acceptable" level; thus encouraging provincial negotiations on rebates. Three negative recommendations were made due to: a) limitations in evidence from open-label, phase two trials (Xalkori advanced non-small cell lung cancer); b) modest progression-free survival, lack of statistically significant overall survival, lack of quality of life data and poor cost-effectiveness (Votrient - soft tissue sarcoma), and; c) unclear clinical benefit and an unacceptable cost-effectiveness model (Treanda - relapsed/ refractory chronic lymphocytic leukemia). In some cases the economic reviews by pCODR included modifications (i.e., shortening time horizons and modifying dose) to the submitted model. **CONCLUSIONS:** The recommendations from pCODR offer new insights into the future of oncology drug reimbursement in Canada. The probability of a positive recommendation appears to increase with randomized controlled trials, positive overall survival and comparators reflecting current care. Finally, the positive recommendations clearly support a continued provincial product listing agreement structure that includes rebates to lower cost-effectiveness. The new pCODR review process highlights the value of strong clinical data and robust cost-effectiveness modeling.

PCN142

COMPARISON OF CANCER THERAPY REIMBURSEMENT DECISIONS MADE IN CANADA TO AUSTRALIA, SWEDEN AND THE UNITED KINGDOM Samjoo IA¹, Grima DT²

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OBJECTIVES: Our aim was to compare recommendations made by the pan-Canadian Oncology Drug Review (pCODR) one year after its launch to other markets. **METHODS:** Publically accessible recommendations were reviewed: Canada (pCODR; <u>www.pcodr.ca</u>), UK (National Institute for Health and Clinical Excellence (NICE), www.nice.org.uk), Sweden (Dental and Pharmaceutical Benefits Agency (TLV), www.tlv.se), and Australia (Pharmaceutical Benefits Advisory Committee (PBAC), www.pbs.gov.au). RESULTS: pCODR had four product reviews in common with NICE, three with TLV, and five with PBAC. pCODR and NICE recommendations were most consistent; both positively recommended Votrient, Yervoy and Zelboraf. Inconsistency was observed for Halaven (pCODR = positive; NICE = negative). Compared to TLV, consistent positive recommendations were noted for Votrient and Yervoy, while inconsistency was observed for Zelboraf (pCODR = positive; TLV = negative). pCODR and PBAC were the least consistent; Votrient (renal cell carcinoma) received a positive recommendation and Votrient (soft tissue sarcoma) received a negative recommendation from both, Afinitor, Sutent, and Yervoy received positive recommendations by pCODR and negative recommendations by PBAC. Only two therapies were reviewed by all four groups: Votrient (renal cell carcinoma) which received a positive recommendation by all and Yervoy which received a positive recommendation by all, except PBAC. **CONCLUSIONS:** For products that were reviewed by pCODR and at least one other agency, the most consistency was observed with NICE. Discordance in recommendations may reflect process differences. For example, pCODR can positively recommend a product with acceptable clinical value conditional on improved costeffectiveness. However, the degree of improvement is not reviewed with the manufacturer; instead it is negotiated with the provincial reimbursement bodies. While other agencies, such as NICE, will specify a patient access scheme with the manufacturer as part of the recommendation process. In addition, pCODR is the only oncology-specific agency in these countries.

PCN143

NOVEL REIMBURSEMENT MODELS FOR CANCER DRUG MARKET ACCESS (2010-2013)

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OBJECTIVES: Cancer drugs are the world's highest selling category of therapeutic products. Due to their premium price and budget impact several new drug reimbursement models have been implemented worldwide by public and private payers. These models have potential implications for coverage and reimbursement of all branded products. This study reviewed recent cancer drug reimbursement models and developed lessons and implications for future reimbursement models and developed lessons and implications for future products. **METHODS:** Reviewed cancer drug reimbursement schemes in developed and emerging markets. Interviewed payers and KOLs to develop lessons and implications for future products. **RESULTS:** Public and private payers worldwide have implemented several new models for cancer drug reimbursement to manage budgets and control costs. In the U.S., private payers are piloting single source compendia and third party protocols (eg. P4 Oncology) to limit off-label use of cancer drugs. In the UK, NICE has successfully negotiated lower price and discounts for the first few cycles of therapy. In Italy, AIFA has implemented registry based patient access for cancer drugs. In India, several manufacturers have implemented novel pricing strategy for the first few cycles

of therapy. In Germany, IQWIG has proposed to use correlations between surrogate endpoints and patient relevant outcomes to determine the value of cancer drugs. Due to the increased cost pressure on payers, such models are likely to inspire novel reimbursement schemes for other branded products. CONCLUSIONS: Cancer drug reimbursement models are setting new benchmark for payers to manage access and control costs. These models have significant implications for other expensive branded products.

PCN144

AN ESTIMATE OF THE HEALTH ECONOMIC BURDEN OF UNSATISFACTORY CERVICAL CANCER SCREENING TEST SAMPLES IN A POPULATION OF WOMEN BETWEEN THE AGES OF 21-65 YEARS IN THE UNITED STATES Stone G

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OBJECTIVES: Unsatisfactory cervical cancer screening cytology samples (Unsats), impose a high financial burden on the health care system. Unsats are important because they are more prevalent in women with invasive cervical cancer. The purpose of this study is to estimate the impact of Unsats on the cost of cervical cancer screening programs as well as on patient outcomes in a U.S. population of women. METHODS: A state-transition Markov model was used to simulate cervical cancer screening and follow-on treatment for a cohort of 1 million U.S. women (21-65 years of age). The screening algorithm used was based on current U.S. cervical cancer screening guidelines which call for primary cytology testing every 3 years for women between the ages of 21 and 65, with an HPV reflex test for those who have an abnormal cytology result. For women over 30, the U.S. guidelines recommend the option of a cytology/HPV co-test every 5 years. Other inputs included U.S. high-risk HPV prevalence; age-specific cervical cancer incidence and associated mortality; age-specific cervical cancer screening and treatment compliance; HPV vaccination rates; and U.S. health care resource cost data. **RESULTS:** Unsats are costly to cytology laboratories as all of the costs associated with reprocessing these samples must be absorbed by the labs. Samples for which reprocessing is unsuccessful impose a greater burden on the health care system in terms of the costs associated with patients returning to physicians' offices for a second sample collection. Some patients who should return for a second collection are lost to follow-up, presenting an opportunity for disease progression. CONCLUSIONS: The Unsat rate associated with a cytology test can significantly increase the effective cost of the test. All costs need to be considered in order to determine the true cost of a cytology test for cervical cancer

PCN145

FIRST RESULTS PROVIDED BY THE RUSSIAN REGISTRY OF BREAST CANCER PATIENTS

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OBJECTIVES: For the contemporary health care, creation of patient registries is a crucial task; first of all they facilitate, from the evidence-based medicine position, the problem of introduction of new effective drugs (including biological drugs). The purpose of this study was to describe the first experience of creation a breast cancer patient registry in the Russian Federation. METHODS: As of 24.07.2012, the Registry included 11,960 patients from 16 regions of Russia. The proportion of Moscow residents is 49.9%. RESULTS: It is found that only in 9.7% of cases included in the Registry breast cancer was detected at stage I. Most commonly the diagnosis was established at the following stages: IIA (27.5%), IIB (17.1%) and IIIA (19.9%). It is worth noting that in the regions the diagnosis of stage I cancer was established more frequently than in Moscow (chi-square=204, p<0.000). Assessment of the distribution of patients in the Registry by expression of estrogen and progesterone receptors (ER/PR) was performed for only 1195 (16.7%) of cases where test results were available. Positive HER-2 status was found in 14.9% of patients in the Registry. In patients with stage I and stage II, a clear prevalence of HER-2 negative cases was found, whereas in patients with stage III and stage IV positive status prevailed. Hormonal anti-progesterone therapy was given to 1345 patients (94.7% of women with overexpression of estrogen and progesterone receptors). 83 patients received treatment with trastuzumab. This is consistent with the total number of HER-2 positive patients (101); the coverage is equal to 82.2% and considered sufficient. CONCLUSIONS: Analysis of the Registry revealed insufficient use of up-to-date immunoassays, including estrogens and progesterone receptors typing, it also showed that it is early stages of the disease when one can expect better clinical effect from the use of hormone therapy and biological therapy.

PCN146

EVALUATION OF DIRECT-TO-CONSUMER ADVERSTISING ACTIVITIES CONCERNING HUMAN PAPILLOMA VIRUS VACCINES THROUGH MASS MEDIA IN THALAND

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OBJECTIVES: The educational content of disease awareness raising activities concerning Human Papilloma Virus (HPV) vaccine that were targeted directly to consumers in Thailand was evaluated in terms of the pattern and quality of the advertised activities. METHODS: The activities targeted at Thai consumers during January 2006 and December 2008, via various mass media including television, magazines, and the internet were identified using health and HPVrelated keywords. The pattern of disease awareness raising activities was assessed by using content analysis method while the quality of educational content was appraised by two pharmacists using evidence-based publications and guidelines from the Cancer Institute of Thailand and medical associations