

By comparison, only 7/88 (8%) of NICE-approved cancer appraisals have been subject to restrictions in addition to the label. **CONCLUSIONS:** Access to anti-cancer drugs under the CDF tends to be more restrictive than those approved by NICE. Thus, attaining NICE approval for CDF-approved drugs could broaden clinical access as well as ensuring reimbursement after the fund is due to close in 2016. Nevertheless, the CDF does provide a formal mechanism under which reimbursement can be provided for off-label use of cancer drugs, which NICE will not consider.

## PCN257

## APPLICATION OF THRESHOLD VALUE FOR COST-EFFECTIVENESS IN RECOMMENDATIONS ISSUED BY AGENCY FOR HEALTH TECHNOLOGY ASSESSMENT IN POLAND FOR CANCER DRUG TECHNOLOGIES

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**OBJECTIVES:** To analyse HTA recommendations for cancer drug technologies issued by Agency for Health Technology Assessment (AHTAPol) in Poland and to verify if official threshold value for cost-effectiveness is respected. **METHODS:** The review of HTA recommendations concerning cancer technologies issued by AHTAPol in the period from January 2012 to March 2014 was preformed. The classification of HTA recommendations based on Raftery's approach labeling them as positive, positive with major or minor restriction and negative was conducted. Decisions and ICURs values from each recommendation were compared to the official threshold value for cost-effectiveness (in Poland defined as 3xGDP for each year) and defined whether the ICUR value is either above or below the official threshold. Other aspects of recommendations, such as criterion for decision, type of RSS implemented and reasons for restrictions were also analysed. **RESULTS:** In the studied period AHTAPol issued 46 recommendations for 35 different cancer drugs (due to the multiplied recommendations for 4 drugs). After review, 32 recommendations with calculated ICUR (with Risk Sharing Scheme (RSS) if implemented) were included in the analysis. For 11 of 13 negative recommendations ICUR values were placed above official AHTAPol's threshold. For 7 of 11 positive recommendations ICUR values were placed below threshold. On the other hand, for 5 of 7 positive recommendations with major restriction ICUR values were placed above official threshold. However, restrictions were related to the unacceptable cost-effectiveness. The same analysis for the ICUR values without implementation of RSS was conducted to compare the results. **CONCLUSIONS:** The official threshold values set in AHTAPol are respected in the majority of decisions for cancer drugs. Cost-effectiveness is one of the most important criterion of decisions made by AHTAPol. Clinical effectiveness, safety and specificity of end-of-life extending medicines were also considered.

## PCN258

## PRICE CONTROL OF OUT-PATIENT CANCER DRUGS IN BULGARIA, 2010-2011: REFERENCE BASED PRICING AND PUBLIC TENDERS VERSUS REFERENCE BASED PRICING ONLY

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**OBJECTIVES:** To compare drug prices and public expenditure of out-patient cancer drugs between two consecutive periods: reference based pricing (RBP) and public tendering at MoH in 2010 and RBP only in a positive drug list (PDL) at the National Health Insurance Fund (NHIF) in 2011. **METHODS:** We compared the prices of the 40 products, which are used in out-patient setting. We used public documents like tender results from 2010 MoH tender and reimbursement list of NHIF in 2011. **RESULTS:** 70% of the products (n=28) were with higher prices, 20% had no price change (n=8) and 10% (n=4) had lower prices in 2011. In 2010, 15% (n=6) had 50% lower prices than same products' prices in the PDL in 2011. For 10% of the products (n=4) in 2010, after tendering, the MoH paid higher prices than the registered prices after RBP. These were patented products, without generic competition. In 2011, NHIF paid BGN 18.591.365 for these 40 drugs. For the same quantities, with MoH 2010 prices, the public expenditure could be BGN 10.788.430 (42% lower). **CONCLUSIONS:** Public tendering achieved lower prices than RBP alone. For patented products, without generic competition, tendering is not the ultimate solution. Tendering should be used with caution, as it can drive some producers out of the market and create non-competitive environment with counter-productive results. Frequent changes of the laws and regulations, without budget impact analysis, is like gambling. Long-term national drug pricing policy is hardly needed and should be strictly followed.

## PCN259

## UNDERSTANDING CAREGIVER BURDEN IN COLORECTAL CANCER: WHAT ROLE DO PATIENT AND CARER FACTORS PLAY?

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**OBJECTIVES:** This study aimed to explore the key determinants of caregiver burden in colorectal cancer (CRC) carers. Specifically we analysed the effect of (i) patient health (ii) care-related activities, and (iii) carer characteristics, as predictors of four distinct aspects of carer burden. **METHODS:** 495 CRC survivors (response rate = 39%) diagnosed 2007-2009 completed a questionnaire which collected information on socio-demographic characteristics, as well as disease and treatment-related factors. General health status was measured using the EORTC QLQ30.228 of these survivors indicated that they had informal carers who were then sent a questionnaire including questions on socio-demographic factors, health status and care-related costs as well as the Caregiver Reaction Assessment (CRA) scale. Hierarchical multiple regression analysis was used to assess the impact of patient factors, care-related activities and carer characteristics on four burden elements within the CRA (family support, finances, schedule, and health). **RESULTS:** 153 carers completed the carer questionnaire and were included in the analysis with their corresponding patients. Patient characteristics and disease-related factors were the strongest predictor of all four aspects of caregiver burden ranging from 14% to 22% of explained variance. Care-related activities also significantly predicted burden scores (explaining an

additional 6% to 11% of variance), however carer characteristics only emerged as a significant predictor of the health burden scale (11% of explained variance). Key individual predictor variables of burden domains included patients' general health status, presence of a stoma, and the time costs associated with care. **CONCLUSIONS:** These results highlight the need to recognise the role that various factors play in determining carer burden. While certain aspects of carer characteristics influence this, patient health and care-related activities have the most significant impact pointing to a need to deliver effective support to those most at risk of carer burden.

## PCN260

## INVESTIGATING THE USE OF PERSONALISED MEDICINE IN CANCER TRIALS - AN UPDATE

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**OBJECTIVES:** Personalised medicine continues to be a hot topic in health care evaluation, particularly in diseases where response to therapy within the patient population is often heterogeneous. The results of an analysis previously presented at ISPOR showed that the proportion of cancer trials investigating personalised medicine rose 7-fold between 2000 and 2010. However, in 2011, this trend appeared to have reached a plateau, with the proportion of cancer trials considering personalised medicine settling at around 15-20%. The aim of this study was to update the previous research to take account of the proportion of cancer trials which included personalised medicine between 2012 and 2013, inclusive, to assess whether this pattern has changed in more recent years. **METHODS:** Terms including 'diagnostic', 'prognostic' and 'biomarker' were used to search ClinicalTrials.gov for all interventional cancer trials which started between 2012 and 2013 and considered the use of individualised medicine. These trials were then compared to those of all interventional cancer trials listed on ClinicalTrials.gov starting in the same period. **RESULTS:** Of all cancer trials analysed between 2000 and 2013, inclusive, 3,664 of 25,203 (14.5%) considered personalised medicine. Although the previous analysis showed a substantial increase in this proportion between 2000 and 2010, this trend does not appear to continue into the current decade. The proportion of trials considering personalised medicine identified in this update was consistent with that seen in 2011, with 17.7% of trials in 2012 and 18.8% in 2013 considering personalised medicine, perhaps signifying a lack of further increase in research interest. **CONCLUSIONS:** Surprisingly, in spite of the apparent drive and enthusiasm for the use of personalised medicine within the medical community, these results indicate that the proportion of such trials may have reached a plateau. Therefore, this might suggest that cancer research is continuing to focus on traditional, non-personalised interventions.

## PCN262

## THE ROLE OF PRIOR BREAST CANCER DIAGNOSIS IN ARTICULATING EXPECTATIONS FOR RECONSTRUCTED BREAST APPEARANCE

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**OBJECTIVES:** Women who undergo mastectomy, whether due to a first-time breast cancer diagnosis or recurrence, are often presented with the option of breast reconstruction. Decisions whether to undergo reconstruction are informed by women's surgery expectations, which develop based on many factors, including past knowledge and experience. The aim of this study was to examine the impact of previous breast cancer diagnosis on a women's approach to expectation-identification of their reconstructed breast appearance. **METHODS:** This study was performed using cross-sectional data as part of a larger field-test. Expectations scales of the BREAST-Q PRO were administered in a clinical setting to breast cancer patients seeking immediate breast reconstruction. Responses were categorized into specific (unlikely, somewhat likely, very likely) or vague expectations (don't know) as the dependent variable. The independent variable was defined as previous or primary diagnosis. Chi Square and one-way ANOVA were performed using SPSS22. **RESULTS:** The study sample (n = 62; response rate, 66%) was characterized by a mean age of 49.6 ± 9.2 years, 82.3% married, 77.4% employed and 79.0% Caucasian. Twenty-three (37.1%) had a history of previous breast cancer diagnosis without mastectomy. Women who had previous breast cancer diagnosis were more likely to select a specific expectation in response to what their new breast (s) would look like in the mirror clothed (ETA squared; 0.11, P=0.011) and unclothed (ETA squared; 0.09, P=0.017) one year after reconstruction. **CONCLUSIONS:** Expectancies guide perception, so that people tend to focus on events that are congruent with their expectations. In our study, women undergoing breast reconstruction were more likely to identify a specific expectation about the appearance of their reconstructed breast if they had been previously diagnosed with breast cancer. More research is needed to determine additional factors that may mediate the development of preoperative surgical expectations. Such information will aid in facilitating patient-physician communication.

## PCN263

## NICE RESTRICTIVENESS COMPARED TO THE MARKET AUTHORIZATION IN ONCOLOGY AND NON-ONCOLOGY REVIEWS

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**OBJECTIVES:** To determine how often NICE recommendations are more restrictive than market authorizations in oncology reviews compared to non-oncology reviews. **METHODS:** 161 NICE Technology Appraisal decisions from 2007-2013 were evaluated; 95 non-oncology and 66 oncology reviews. For each generic drug included in a review, the corresponding brand and market authorization was retrieved from the EMA or MHRA. NICE positive decisions were compared to the market authorizations. Any decision that included language that restricted the population eligible for treatment or reimbursement for a given therapy was categorized as "recommend with restrictions." NICE positive decisions that were not more restrictive than the market authorizations were categorized as "recommend." Negative decisions were categorized as "do not recommend." **RESULTS:** Oncology reviews were more likely to