By comparison, only 7/88 (8%) of NICE- approved cancer appraisals have been subject to restrictions in addition to the label. ODE resulted in 100% 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 Zawojska A, Matusewicz W
Agency for Health Technology Assessment in Poland (AHTAPol), Warsaw, Poland

OBJECTIVES: To analyse HTA recommendations for cancer drug technologies issued by the Agency for Health Technology Assessment in Poland between January 2012 and March 2014 to determine 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 performed. The classification of HTA recommendations was done according to the level of support for reimbursement and by aligning 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 criteria for decision, type of RSS implemented and reasons for restrictions were also analysed. RESULTS: In the studied period AHTAPol issued 67 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 13 of these recommendations, ICUR values were 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 values from each recommendation were compared to the official threshold value for cost-effectiveness is respected.

PCN258 PRICE CONTROL OF OUT-PATIENT CANCER DRUGS IN BULGARIA, 2010-2011: REFERENCE BASED PRICING AND PUBLIC TENDERS VERSUS REFERENCE BASED PRICING ONLY Djambazov SN1, Yekorov TY, Petrov D2
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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 public 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 outpatient setting. We used public documents like tender results from 2010 MoH tender and reimbursement list of NHIF in 2011. RESULTS: 70% of the products were with higher prices than equivalent products in PDL and 10% (n=10) had lower prices in 2011. In 2010, 15% (n=6) had 50% higher prices than the same products’ prices in the PDL in 2011. For 10% of the products (n=4) in 2010, MoH paid double prices than the PDL in 2011. These were patented products, without generic competition. In 2011, NHIF paid BGN 18,591.365 for these 40 drugs. For the same quantities, MoH 2010 prices, the public expenditure could be BGN 10,788 403 (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? Manuski B, Walker-Smith J, Sharp L
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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 sociodemographic characteristics, as well as disease and treatment-related factors. General health status was measured using the EORTC QLCQ30.228 of these survivors indicated that they had informal carers who were then sent a questionnaire including information on socio-demographic factors, health status and disease-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, financial strain, emotional distress, and health). RESULTS: 153 carers completed the care 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 around 50% to over 80% 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 caregiver burden. While this is beyond the scope of this study, 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. In response to therapeutic needs, 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 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 patient characteristics as a major restriction ICUR values were placed above official threshold value 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 as a major restriction without ICUR values was place above official threshold value in 17.1% 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 oncology market, recent data 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.

PCN261 THE ROLE OF PRIOR BREAST CANCER DIAGNOSIS IN ARTICULATING EXPECTATIONS FOR RECONSTRUCTED BREAST APPEARANCE Scott AM, Watson J, Maizza M
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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 patient’s own 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 preferred breast appearance. METHODS: Two years of patient-physician communication. To determine how often NICE recommendations are more restrictive than market authorizations in oncology reviews compared to non-oncology reviews: To determine how often NICE recommendations are more restrictive than market authorizations in oncology reviews compared to non-oncology reviews.

Methods: A total of 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 of the same medicine. carcinoma. 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 (categorical ETA squared; 0.11, I2=0.01) and unclothed (ETA squared; 0.09, P=0.017) one year after reconstruction. CONCLUSIONS: Expectancies guide perception, so 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 surgery expectations. Such information will aid in facilitating patient-physician communication.

PCN262 NICE RESTRICTIVENESS COMPARED TO THE MARKET AUTHORIZATION IN ONCOLOGY AND NON-ONCOLOGY REVIEWS Saka A, Westbrook L, Rubenstein E, Daniel K, Ho YS, Coastal Medical Consulting Inc., New York, NY, USA

OBJECTIVES: To determine how often NICE recommendations are more restrictive than market authorizations in oncology reviews compared to non-oncology reviews: To determine how often NICE recommendations are more restrictive than market authorizations in oncology reviews compared to non-oncology reviews.

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be issued a “do not recommend” decision for non-oncology reviews (56% vs. 16%); p< 0.05. Over time these significances disappeared in most of the “do not recommend” decisions for non-oncology reviews and oncology reviews, though rates of “do not recommend” decisions have increased for oncology reviews since 2008. There were no differences in the rates of “recommend” and “recommend with restriction” decisions between oncology and non-oncology reviews (p= 0.87). Overall there was a significant decrease in the rates of “recommend with restrictions” decisions for oncology reviews (p= 0.07), but no statistical trend in non-oncology reviews. CONCLUSIONS: NICE has started issuing more “do not recommend” decisions for oncology reviews but has not for non-oncology reviews, but there was no difference in the overall rates of “recommend with restrictions” decisions. Over time, NICE appears to be replacing “recommend with restriction” decisions with “do not recommend” decisions in oncology reviews, but this did not pass traditional significance levels.

PCN264
SYSTOMATIC REVIEW OF ECONOMIC EVALUATIONS IN CANCEROLOGY IN BRAZIL BETWEEN 1980 AND 2013
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Nowadays, economic evaluation has been increasingly used in health care decision-making in Brazil. The Brazilian economic evaluation literature in cancerology is unknown. OBJECTIVES: This systematic review aims to identify and characterize the economic evaluation studies in cancerology conducted in Brazil. METHODS: Ten online databases (MEDLINE (PubMed), EMBASE, Latin American and Caribbean Literature on Health Sciences Database (LILACS), Scientific Electronic Library Online (SciELO), National Health Information System (SISDAT), National Health Information System (SISBARES), Web of Science, and the Sistema de Informação da Rede Brasileira de Avaliação de Tecnologias em Saúde (SISBRAE)) were systematically searched. We also performed manual search. We selected partial and full economic evaluation studies in cancerology, where at least one of the authors was affiliated to a Brazilian institution. The authors performed the data extraction independently. Disagreements were resolved through discussion or through consultation with a third reviewer. The study characteristics were summarized in figures and summary tables. RESULTS: A total of 11946 records were identified. Fifty six articles met inclusion criteria, of these, 33 (59%) were full and 23 (41%) were a partial economic evaluation. The cost-effectiveness analysis was the most used (27%). There was an increase in the number of publications over the years, especially after 2006. Researchers from the Southeast region of Brazil were responsible for the majority of the publications (82%). Cancers most frequently studied were breast cancer (37%), followed by cervical cancer (16%), lung cancer (12%) and colorectal cancer (9%). The technologies most studied were medications (34%). CONCLUSIONS: The expansion of the analysis to all included studies was not possible. The majority of the studies were based on secondary data sets. However, Zykynin appreciated the cost-effectiveness of the local product for a limited reimbursement even though budget impact was high. CONCLUSIONS: Since implementation of Taiwan’s NHI reforms in January 2013, cardiovascular and oncology drug approvals decreased by 36% compared with agreements with western agencies from 2009-2010, placing an emphasis on budget impact. However, this analysis was constrained by its small sample size, and limited therapy areas.

PCN267
EXPANDED DATA SETS FOR HTA DECISION-MAKING IN ONCOLOGY: DO THEY HELP TO ACHIEVE POSITIVE APPRAISALS?
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OBJECTIVES: Phase III, randomised controlled trials remain the gold standard for health technology assessment (HTA) submissions. Data sets may be supplemented with evaluations from other sources, in particular clinical trial evidence. However, the influence of expanded data sets on HTA appraisals is unclear. METHODS: We reviewed recent National Institute for Health and Care Excellence (NICE) and Canadian Agency for Drugs and Technologies in Health (CADTH) HTA submissions to determine the frequency and type of expanded data sets. We then evaluated the influence of expanded data sets on HTA decisions. RESULTS: There were 30 relevant appraisals on the NICE website covering a range of cancer types. Of these, 14/30 made use of expanded data sets featuring Phase II trials, observational studies, meta-analyses and/or mixed treatments. Disagreements among the three agencies seen for 18/30 submissions. Reasons for using expanded data sets included: agency concerns over Phase III studies, lack of long-term or head-to-head data and limited Phase III data. Where additional data were included, around one third (5/14 cases, 35%, 5/30 [16.7%] overall) appeared to have directly influenced the final decision. Over all, positive appraisals were less frequent for submissions that featured expanded data sets compared with submissions featuring Phase III data only (2/14 [14.3%] vs 9/36 [25.0%]). Conclusions: We found that expanded data sets feature in nearly half of recent NICE oncology HTA assessments. However, additional data appear to have influenced only in five appraisals by NICE and PHMR. Expanded data sets have a place in contributing to HTA decision making, but overall, rigorous Phase IIIRCT data remain essential to obtain a positive HTA appraisal.

PCN268
THE LIFE AND DEATH OF THE END OF LIFE TREATMENT APPRAISAL CRITERIA IN NICE TECHNOLOGY APPRAISALS
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OBJECTIVES: Since January 2009, NICE in the UK allows end of life (EOL) treatments to cover the upper end (EOL/day) of the threshold for some ICERs. We performed an exploratory cost-effectiveness analysis of EOL treatments to determine the threshold for EOL/day treatments with 95% confidence intervals. RESULTS: EOL treatments were crucial for PHMR approval overall. CONCLUSIONS: We found that EOL submissions feature in nearly half of recent NICE oncology HTA assessments. However, additional data appear to have influenced only in five appraisals by NICE and PHMR. Expanded data sets have a place in contributing to HTA decision making, but overall, rigorous Phase IIIRCT data remain essential to obtain a positive HTA appraisal.