recommendations. Its Dutch counterpart, ZI, issued only 8% of negative decisions to TCTs. The mode for a success rate in the Netherlands was special policy that enable reimbursement of TCTs without CTA.

PCN251 THE CANCER DRUGS FUND: A SYSTEMATIC ANALYSIS OF THE REQUIREMENTS FOR INCLUSION ON THE ENGLISH NATIONAL LIST OF DRUGS FOR PRIORITY FUNDING

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OBJECTIVES: The price of a medicine should reflect the value it offers to patients, the health care system and society more broadly. However, with current pricing, manufacturers often set the price of a product based upon the cost per unit of that product. This may result in a price being set which society considers as too high. This paper aims to investigate whether the value can lead to patients being denied access to medicine in certain indications. METHODS: The implementation of a pricing model where there is differentiation of a medicine across indications, line of therapy or if used as a mono/combination therapy requires the use of real world drug utilisation data. The Personalised Reimbursement Models project is at the forefront of the development and implementation of innovative pricing in the UK. This project includes identifying and developing the indicative thresholds required in order to introduce Multi-Indication Pricing (MIP) into the NHS in the UK. We have worked alongside NHS Trusts and national bodies in a joint working project to validate and test the utility of the Systemic Anti-Cancer Therapy (SACT) data. RESULTS: This joint working project demonstrates that SACT has the potential to allow implementation of MIP in England. CONCLUSIONS: Following completion of this work we hope SACT will be used to introduce MIP in England - this will enable the comprehensive administration of the burden of drug collection for commercial schemes. The lack of comparative data was critiqued as introducing considerable uncertainty for the value they provide in each of their uses and ensure that patients are not disadvantaged due to having a condition potentially treatable by a product with multiple indications.

PCN253 ONCOLOGY PRODUCTS IN THE AMNOG PROCESS – LEARNINGS FOR A SUCCESSFUL DOSSIER SUBMISSION

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OBJECTIVES: Since AMNOG reform has taken effect 3.5 years ago, 78 dossiers have been evaluated by the G-BA. Especially with oncology agents, 28 products have started the process and a G-BA has finalized decisions for 25 dossisters. In 20 cases additional benefit was granted. Therefore, the success rate of oncology products is 80% and much higher than the success rate of non-oncology products (29%). METHODS: An analysis of all oncology assessments will reveal key drivers responsible for the positive assessments by IQWiG and G-BA. Beside the study design (R2G vs. indirect comparison), and comparator choice the analysis will focus on submitted end-points. It will be evaluated which endpoints contribute most in oncology indications to additional benefit. RESULTS: Additional benefit is assessed based on patient relevant endpoints (mortality, morbidity, quality of life & safety). More than 55% of submitted endpoints fall in the safety category, followed by morbidity (approx. 30%), mortality (approx. 10%) and quality of life (approx. 5%). The most important endpoints were OS, where the G-BA granted additional benefit in 18 out of 20 dossiers primarily based on OS data. In terms of morbidity, PFS, ORR and “Time to Progression” are the top three most submitted morbidity endpoints; however, only “Time to Progression” led to additional benefit in 2 out of 3 cases. Important observations were: (1) Cessation of life conditions as endpoints, (2) endpoints should be used for all drugs considering the same qualifications. CONCLUSIONS: OS will continue to be the most additional benefit contributing endpoint in oncology. In the absence of OS, PFS will not help in the overall additional benefit decision by G-BA, whereas the MNI can justify PSF to be patient relevant according to IQWiG methodology. Although QoL is an accepted endpoint by G-BA, due to the high methodological standards set by G-BA and IQWiG, manufacturers should de-prioritize this endpoint.

PCN254 MEDIA COVERAGE OF THE NICE FIRST DRAFT CONSULTATION GUIDANCE FOR TRASTUZUMAB EMANUSMINE (KADCYLA) IN BREAST CANCER

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OBJECTIVES: The National Institute of Health and Care Excellence (NICE) makes recommendations on which drugs the National Health Service (NHS) should fund, with cost-effectiveness being a key criterion. There have been critical media reactions toward NICE appraisals that recommend against funding drugs (particularly oncology) because the most memorable example of which relates to the funding of Herceptin in early-stage breast cancer in 2005. This research aimed to evaluate how the media currently report NICE decision-making, focussing on the NICE appraisal guidance document for the first time. METHODS: A national and regional newspaper websites, UK broadcasters, press agencies, pharmaceutical trade and medical publications were screened for any articles published between 23rd-25th April 2014 regarding this NICE draft guidance from which key criteria were extracted and compared. RESULTS: 19 articles were extracted (6 national newspapers, 6 regional newspapers, 3 broadcasters, and 4 other). 7/19 articles primarily focussed on the reaction of a patient/doctor, all of whom were particularly critic of the NICE decision. 3/19 focused on the high proposed cost of the new drug, 2 of which were critical of the pharmaceutical company. 9/19 followed the format of briefly summarising the decision and drug, with the majority of the article comprising reactions from various sources. However, there was an overall numerically higher number of sources in each article criticizing NICE (38, mean 2.0 per article) than those defending the NICE decision (21, mean 1.1 per article). CONCLUSIONS: NICE decisions not to fund oncology drugs still seem to be predominately faced by a hostile media reception that focus more on patient reactions than the difficulties of how to allocate finite health care resources to best optimise care in the NHS.

PCN255 COMPARING HOW SINGLE ARM PHASE II TRIAL DATA CAN SUPPORT APPROVAL OF ONCOLOGICS BY EUROPEAN HEALTH TECHNOLOGY ASSESSMENT BODIES

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OBJECTIVES: The European Medicines Agency (EMA) approved 15 oncologics across 24 indications based on pivotal single-arm Phase II data (Macaulay, ISPOR Dublin 2013). Approval was typically granted for indications in which there was no therapeutics. This paper examines the evidence and cost required to support an approval by the EMA. CONCLUSIONS: There is significant variability in the definition of evidence and cost required to support an approval by the EMA. These differences may reflect the underlying desire to support a broad range of oncologics. The lack of comparative data was critiqued as introducing considerable uncertainty for the value they provide in each of their uses and ensure that patients are not disadvantaged due to having a condition potentially treatable by a product with multiple indications.
By comparison, only 7/88 (8%) of NICE-approved cancer appraisals have been subject to restrictions in addition to the label. CDF provides 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 off-label treatment can be provided for off-label use of cancer drugs, which NICE will not consider.

PC257
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 AOTM. Method: A total 36 recommendations of AOTM for cancer drugs between 2002 and 2014 were assessed. 12 were official AHPoA’s recommendations and 24 were official AHTA-Pol’s threshold. RESULTS: The review of HTA recommendations concerning cancer technologies issued by AHTA-Pol in the period from January 2012 to March 2014 was performed. The classification of HTA recommendations was performed based on a payment approach labeling them as positive, positive with major with minor or negative. The final expectation of HTA recommendations was calculated with the threshold with major with minor or negative and was conducted. Decisions and ICUR values from each recommendation were compared to the official threshold value for cost-effectiveness (in Poland defined as 3GDP for each year) and defined whether the ICUR value is below the official threshold. Other aspects of recommendations, such as for consideration and type of ICUR implemented and reasons for restrictions were also analysed. RESULTS: In the studied period AHTA-Pol issued 21 positive recommendations for 35 different cancer drugs (due to the multiplied number of recommendations for 4 drugs). After review, 32 recommendations with calculated ICUR (with Risk Sharing Scheme (RSS) if implemented) were included in the analysis. For 91% (13/14) of positive recommendations, the results were above the official AHTA-Pol’s threshold. For 11 of 11 positive recommendations ICUR values were placed below the threshold. On the other hand, only 5 of 7 positive recommendations with ICUR values were placed above the official AHPoA’s threshold. However, 7/11 with 77% of restrictions were related to the unacceptable cost-effectiveness. The same analysis for ICUR values without implementation of RSS was conducted to compare to the official threshold. CONCLUSIONS: The threshold official values set in AHTA-Pol are respected in the majority of the case of all interventional cancer trials on the basis of the law and regulations, with the exception of the cases which means the most important criterion of decisions made by AHTA-Pol. Clinical effectiveness, safety and specificity of off-label extending medicines were also considered.

PC258
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 outpatient setting. We used public documents like tender results from 2010 MoH tender and reimbursement list of NHIF in 2011. RESULTS: 70% (8/11) of the tender prices were with higher prices than reference price of RBP and 10% (n=4) had lower prices in 2010. In 2015, 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, the MoH paid higher prices than reference price of RBP. 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 10.788.410 (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.

PC259
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 sociodemographic characteristics, as well as disease and treatment-related factors. General health status was measured using the EORTC QLQ-C30. The study was the aim of the study was to examine the potential predictors of caregiver burden. 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 activities, carer role, patient care, 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 27% to 83% 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.

PC260
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. This study aims to assess the response to therapy and 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 been reversed. Objectives: To investigate whether this trend has continued into 2011. Methods: We compared the number of clinical trials listed on ClinicalTrials.gov starting in the same period. RESULTS: Of all cancer trials analysed between 2000 and 2010, 3,664 of 25,203 (14.5%) considered personalized medicine. The proportion of trials including personalisation increased from 2000 to 2010. CONCLUSION: This study has shown that the proportion of cancer trials considering personalised medicine has decreased in the last few years. Further research is needed to determine additional factors that may mediate the development of these trends.

PC262
THE ROLE OF PRIOR BREAST CANCER DIAGNOSIS IN ARTICULATING EXPECTATIONS FOR RECONSTRUCTED BREAST APPEARANCE
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OBJECTIVES: Women who undergo mastectomy are often informed that 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 recent breast cancer experience. The aim of this study was to examine the role that breast cancer experience has on women’s reconstruction expectations. METHODS: A survey was administered in a clinical setting to breast cancer patients seeking immediate post-mastectomy breast reconstruction. Decisions whether to undergo reconstruction are informed by women’s expectations. Our expectations of appearance were guided by the presence of additional criteria, such as the patient’s gender, age, and previous breast surgery history. 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 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 in response to 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.

PC263
NICHE 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 Appraisals 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 for the same drug to determine whether the NICE recommendation included language that restricted the population eligible for treatment or reimbursement for a given therapy was categorized as “recommend with restrictions.” NICE positive decisions were 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 be restrictive than non-oncology reviews.