determination. 22 drugs met NICE's EOL-SPP for the indication for which they were being appraised. Twelve of these drugs had the EOL-SPP criterion applied to the only indication for which they were licensed. The EOL-SPP criterion was applied to the cumulative populations of ten drugs which had marketing authorization for more than one indication. The seven drugs that did not meet the EOL-SPP criterion all had individual indications which were within the number of what is considered acceptable (≤7,000), but had total cumulative populations that were greater. Two STAs in particular stand out. The appraisal committee accepted that panitumumab met the EOL-SPP criterion for its current indication but noted that the EMA recommended a marketing extension which would raise the expected patient population to 10,000. In its final appraisal determination for abiraterone NICE overturned its original decision that the drug did not meet the EOL-SPP criterion, even though it noted that abiraterone may be recommended for a marketing extension for a greater patient population. **CONCLUSIONS:** There is no evidence to suggest NICE applies the EOL-SPP to the cumulative populations of currently licensed indications plus potential future indications.

PCN150

COMPARISONS OF QALYS GAINED, COST PER QALY GAINED AND ASMRS FOR 38 ANTICANCER DRUGS IN FRANCE AND THE UK: VIVE LA DIFFERENCE?

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OBJECTIVES: To compare the contrasting approaches in France and the UK for assessing the value added by new drugs **METHODS:** We reviewed the technology appraisals performed by the National Institute for Health and Clinical Excellence (NICE) on 38 anticancer drugs in the UK from September 2003 to January 2012. Estimates of the quality-adjusted life-years (QALYs) gained and incremental cost per QALY gained were then compared the assessments of the Amélioration du Service Médical Rendu (ASMR) made by the Haute Autorité de Santé (HAS) in France for the same drugs in the same clinical indications. **RESULTS:** In the UK, the estimates of QALYs gained ranged from 0.018 to 1.85 and estimates of incremental cost-per QALY from £1800 to £458,000. The estimate of incremental cost per QALY was a good predictor of the level of restriction imposed on the use of the drug concerned. Patient access schemes, which normally imply price reductions, were proposed in 45% of cases. In France, the distribution of ASMRs was 1, 16%; 2, 8%; 3, 21%; 4, 24%; 5, 24%; and uncategorized/ non-reimbursed, 8%. Since ASMRs of 4 and above signify minor or no improvement over existing therapy, these ratings imply that, in around half the cases, the drugs concerned would face price controls. Overall, the assessments of value added in the two jurisdictions produced very similar results. A superior ASMR rating was a good predictor of both higher QALYs gained and a lower incremental cost per QALY. **CONCLUSIONS:** We conclude that, despite the contrasting approaches employed in France and the UK for assessing the value added by new drugs, the overall assessments of value added produced very similar results. However, the implications of these assessments for patient access to, and prices of, anticancer drugs in the two jurisdictions require further investigation.

PCN151

HTAS FOR THE DEADLIEST DISEASES: WHAT CAN WE LEARN FROM MULTI-NATIONAL COMPARISONS OF ONCOLOGY AND CARDIOLOGY HEALTH TECHNOLOGY ASSESSMENTS?

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OBJECTIVES: To examine the similarities and differences in the HTAs conducted in 6 countries in the last 5.5 years in the areas of cardiology and oncology, the therapeutic areas of greatest mortality. **METHODS:** We reviewed and abstracted information from 768 cardiology and 960 oncology HTAs conducted from January 1, 2007 to June 23, 2012. Our primary focus was those made by the following public organizations: Canadian Agency for Drugs and Technology in Health, Haute Autorite de Sante, Institute for Quality and Efficiency in Health Care, National Institute for Clinical Excellence, Pharmaceutical Benefits Advisory Committee, Medical Services Advisory Committee, and the Agency for Healthcare Research and Quality. For comparative purposes and overall interest, we also studied the HTAs of the following private American organizations: BlueCross BlueShield Technology Evaluation Center, California Technology Assessment Forum, Drug Effectiveness Review Program, Healthcore/Wellpoint, Institute for Clinical and Economic Review, and the MedCo Research Institute, and the multinational Cochrane Collaboration. Finally, we looked at the American Recovery and Reinvestment Act generated CER grants recently made by the federal government to the National Institutes of Health and the Department of Health and Human Services to determine any new directions in the US. Cardiology HTAs were divided into 12 sub-therapeutic categories; oncology 18 for ease of analysis. Variables analyzed included specific subject of HTA and analytic methods, date of release, and results. **RESULTS:** Market entry of drugs and selected devices tended to affect HTA content and timing; country processes for review also affect these variables and results. HTAs of other single interventions and multiple modality comparisons were more variable as to timing, content, and results. **CONCLUSIONS:** Both the commonalities and differences found in the HTAs lend themselves to the examination of potential "economies" of evidence assessment and bases for optimal patient care. The authors provide suggestions for policy makers.

PCN152

PATIENT-RELEVANT ENDPOINTS (PRE) IN ONCOLOGY - CURRENT ISSUES IN THE CONTEXT OF EARLY BENEFIT ASSESSMENT (EBA) IN GERMANY: AN INDUSTRY PERSPECTIVE

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OBJECTIVES: The German AMNOG health care reform includes a mandatory EBA of innovative medicines at launch. As per German social code, EBA is based on registration trials and must include evaluation of the patient-relevant, therapeutic effect of the new medicines compared to an appropriate comparator as defined by the Federal Joint Committee (G-BA). Current EBA decisions released have unveiled issues regarding the acceptance of some PRE as G-BA and IQWiG are grading the endpoints, focusing on overall survival (OS) as the preferred endpoint in oncology. **METHODS:** A task force under the auspices of the German Association of Research-based Pharmaceutical Companies (vfa) was appointed. Members were experienced German outcomes research, medical, HTA and biostatistics researchers in industry. After agreement on core assumptions developed and outlined by the Task Force, a draft position was prepared. Input on iterative versions was solicited from a panel of reviewers from industry and external stakeholders. **RESULTS:** Distinctive features of registration trials in oncology need to be considered when these studies form basis for EBA, especially in cancer indications with long post-progression survival time; and with several consecutive therapeutic options available following progression. Besides, ethical committees, caregivers and patients often demand cross-over-designs diluting over the treatment effect on OS. Also, regulatory authorities require evaluation of morbidity-related study endpoints including survival of patients without their disease getting worse (i.e., progression-free survival). Fear of progression is a key feature in oncological conditions. Furthermore progression usually requires treatment changes, another strong indicator for its relevance to patients. **CONCLUSIONS:** PRE in oncology depend on tumor- and tumor-stage-specific factors. For decades, endpoints have been thoroughly evaluated, resulting in specific guidelines and clinical trial programs that were developed in-line with regulatory guidance. This extensive knowledge and experience should be fully acknowledged during EBA when assessing the patient-relevant benefit of innovative medicines in oncology.

PCN153

APPLICATION OF REAL WORLD DATA TO INFORM A BREAST CANCER DECISION - ANALYTIC MODEL IN AUSTRIA AND THE U.S - PRELIMINARY OUTCOMES OF DATA COLLECTION

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OBJECTIVES: A Breast Cancer Outcomes & Policy (BCOP) microsimulation model is being developed to evaluate the 21-gene recurrence score assay that guides adjuvant chemotherapy in Austria. The goal is to adapt the model to a United States (US) context using real-world data from the Huntsman-Cancer-Institute (HCI) in Utah. We aim to study the impact of real-world data and country-specific settings on cost-effectiveness results. **METHODS:** The BCOP-model simulates a hypothetical cohort of 50year old women over a lifetime time horizon using a discrete-event-simulation. To inform this model, a cohort of early breast cancer patients was identified at the HCI based on ICD-9 codes(174.0-174.9) and inclusion in the HCI registry for invasive breast cancer from 2005-2010. Patients were included with stage I to IIIa disease at diagnosis, documented curative intent surgery, use of endocrine therapy, and lack of HER2 directed therapies. Patients receiving adjuvant chemotherapy were identified. Price for chemotherapy was based on average wholesale price (AWP). **RESULTS:** A total of 367 patients with early stage breast cancer were identified with a mean age of 58.2 years. There were 123 patients (33.5%) treated with adjuvant chemotherapy. Among the 123 patients treated with chemotherapy, 21%, 64.2% and 14.6% were stage I, II and IIIa respectively; which comprised 12.3%, 57.7%, and 64.3% of all stage I, II, and IIIa patients, respectively. The predominate chemotherapy regimen was doxorubicin and cyclophosphamide with or without paclitaxel for 72% of patients. The AWP for this regimen is $4476 with and $1507 without paclitaxel, respectively; the AWP of Oncotype Dx is $4175. One of the challenges faced during model development was that many of the variables needed require chart reviews. **CONCLUSIONS:** Extraction of data from a real-world breast cancer cohort provided reference data on treatments and costs to inform the BCOP- model.

PCN154

ARE POPULATION-BASED REGISTRIES A SUITABLE TOOL FOR OUTCOMES RESEARCH IN CANCER? EXPERIENCES FROM FOUR REGISTRIES

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OBJECTIVES: Population-based registries provide insights into quality of care and inform reimbursement decisions. This study aims to investigate whether registries are a suitable tool for outcomes research in assessing drug use and real-world cost-effectiveness in cancer. **METHODS:** We used four Dutch population-based registries to conduct outcomes research. Patients for the registries were included regardless of prognosis or treatment: 55% and 40% of all Dutch patients in metastatic renal cell cancer (mRCC) and three haematological cancers, respectively.

Data were retrospectively collected at several points in time from medical records and hospital information systems on baseline characteristics, treatments, dosages, treatment response, survival, adverse events and resource use. All patients entered the registry at time of diagnosis. **RESULTS:** Our registries contained information of 615 mRCC and 3093 haematological cancer patients (non-Hodgkin, multiple myeloma, and chronic lymphocytic leukaemia). They provided important information about how patients, including those regularly excluded from clinical trials, are treated in daily practice. However, important data, including prognostic information, was commonly missing (e.g. 40-55% missing performance status). Furthermore, patients treated with the drug of interest were not comparable to patients not treated with this drug. Moreover, only small numbers of patients received the drug of interest (mRCC: N=34; non-Hodgkin: N=35), and many patients received different drugs in various combinations and treatment sequences in haematological cancers. This, in combination with the inability to fully correct for confounding, complicates the estimation of a real-world incremental cost-effectiveness estimate. **CONCLUSIONS:** Our registries provided important information to physicians and policymakers to enhance quality of care and facilitate evidence-based decision making. Although population-based registries include high numbers of patients, it remains a challenge to obtain sufficient numbers of similarly treated and comparable patients. Therefore, it is inevitable to use data synthesis in combination with comprehensive modelling techniques to obtain valid real-world incremental cost-effectiveness estimates.

PCN155

IS SALE OF TOBACCO AND SMOKING PREVALENCE PREDICTORS OF FUTURE LUNG CANCER INCIDENCE?

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OBJECTIVES: Smoking is a leading cause of early dead and morbidity in the Western World. The purpose of this study is to evaluate how tobacco sales and tobacco survey data correlates with lung cancer incidence in the Danish population. It is estimated that up to 86% of lung cancer cases in developed countries are smoking related. **METHODS:** Lung cancer incidence data from 1943-2009 are from Nordcan (www.ancr.nu). Sale of tobacco (cigarettes/inhabitant) 1920-2010. Smoking habit surveys from 1953-2010, annually from 1969. Lung cancer incidence is age standardized to the Nordic population (ASR(N)), and is in rate per 100.000/year. Correlations are analyzed with Spearman's rho with SPSS18. **RESULTS:** The strongest correlation (spearman's rho = 0.92, $p<0.0001$) is found between sale of cigarettes and incidence of lung cancer with a lag time of 24 years. The correlation between lung cancer and the proportion of the population that smokes is well correlated for men (0.8, $p<0.0001$, lag time=20 years). Female smokers and lung cancer are with a lag time of 5-26 years negatively correlated, but correlates positively when the lag time is more than 27 years, the best correlation being 0.732 ($p=0.039$, lag time=35 years). **CONCLUSIONS:** The correlation between lung cancer incidence and the sale of cigarettes is better than for the proportion of smokers. This might be because sale gives a better estimation of the overall exposure in a form of population "pack years". The negative correlation between the proportion of female smokers and lung cancer, and the change to a positive correlation when a longer lag time is applied can be either a true finding that might be explained by longer development time in females. Or it could be a result of changes in the accuracy of the proportion, or a result of changes in the age pattern.

PCN156

VALUE BASED PRICING IN THE UK; INDUSTRY STAKEHOLDERS' PERSPECTIVES

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OBJECTIVES: The new value-based system of pricing branded medicines in the UK is nearing the launch phase with unresolved concerns towards developing the new pricing framework and executing the system. This study identifies the strategies proposed by stakeholders for the successful implementation of VBP and also determines the 'relative importance weights' of additional value-elements i.e., burden of illness, innovation and societal benefit introduced in the new pricing framework. **METHODS:** In-depth qualitative and survey-based interviews were conducted with 23 experts identified in pharmaceutical industry, NHS and SMC advisory committees, NHS hospitals and pharmacies. **RESULTS:** Pharmaceutical industry should adapt to a new model that brings innovation in R&D, addresses unmet need and demonstrates the value of a new drug by gathering real-world evidence. Government or payers should proactively publish guidelines before the launch or propose a transitional arrangement for pharma in 2014. The local uptake of medicines should be encouraged by introducing national settlement schemes and incentivizing the local commissioning groups. It is possible that government and pharmaceutical industry will direct more efforts towards improving the interaction between prescribers and patients for gathering real-world evidence. The results also indicated that clinical-effectiveness and cost-effectiveness will remain the prime metric in valuation process, however, burden of illness and innovation may carry more weight than other value-elements. Societal benefit still needs to be broadly defined; and innovation should ultimately translate into improved clinical efficacy. The study also highlights the impact of VBP on each stakeholder group and across disease areas with a focus on primary care and oncology. **CONCLUSIONS:** The stakeholders still lack the clear understanding of VBP and believe that ultimately it might be restructuring of the existing system given the limited time left for its implementation. Even though the new pricing framework includes additional criteria, pricing decisions are anticipated to be made on a case-by-case basis eventually.

PCN157

CONCEPTUAL FRAMEWORK FOR THE EVALUATION OF PATIENT ACCESS SCHEMES (PAS) IN THE EU

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OBJECTIVES: Patient access or risk sharing schemes (PASs) have recently been increasingly used, enabling easier and swifter access to new treatments, especially in oncology. However, PASs frequently do not deliver the required results. The aim was to create a conceptual framework that allows the selection of the most appropriate PAS in different countries. **METHODS:** A targeted literature review has been conducted to identify PAS specific literature in oncology. Based on the review and the evaluation of the currently implemented PASs in the EU, a three-level conceptual framework has been constructed. It is based on a list of criteria identified as country-specific prerequisite for the different types of PASs. Each criterion can be achieved by different tools/techniques, each with a list of basic requirements. PASs for each country can be evaluated using simple scoring system for each criterion. The proposed framework has been validated by EU industry experts and payer's representatives and tested for the UK and Hungary. **RESULTS:** The literature review identified large number of abstracts and studies; however only 14 met the inclusion criteria. These were mainly from the UK and US. The criteria evaluated authorities' roles and responsibilities, transparency throughout the negotiation process and implementation phase for all stakeholders, presence of trust and cooperation among payers and manufacturers, availability of budget, clear patient pathways, data availability, administration capacity and appropriate incentives for the stakeholders. The test results were in accordance with the expert's views and emphasized the insights from recent experiences and case studies. **CONCLUSIONS:** The conceptual framework offers a good starting point for the evaluation of the potential success of the different PASs in oncology in a given country. Future steps could include extension of therapeutic area, incorporation of relative weights for the criteria and extending the countries used for validation.

PCN158

ADHERENCE TO HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR-2 (HER2) TESTING & ADJUVANT TRASTUZUMAB TREATMENT GUIDELINES IN A CANADIAN PROVINCE

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OBJECTIVES: We evaluated the use of confirmatory HER2 fluorescence in situ hybridisation (FISH) and predictors of trastuzumab use in early-stage breast cancer (ESBC) in the province of Ontario. The adherence of practice patterns to provincial adjuvant trastuzumab treatment guidelines and national HER2 testing consensus guidelines was assessed. **METHODS:** A retrospective cohort of ESBC patients diagnosed in 2006-7 was identified in the Ontario Cancer Registry (OCR). HER2 test type, sequence, result(s) and status, tumour grade and hormone receptor status were determined from centrally-held (OCR) pathology reports. Trastuzumab treatment was determined from provincial cancer agency records. Demographic, local health integration network (LHIN), surgical, prior radiological and anthracycline treatment and comorbidity data were determined from administrative data sources. Logistic models were used to estimate adjusted odds ratios for factors associated with guideline adherence. **RESULTS:** The first HER2 test result was the largest predictor of confirmatory testing, with HER2 equivocal tumours being significantly more likely to be retested vs. positive (OR 116 [79, 169]). Confirmatory testing varied by LHIN but not by age. Patients diagnosed with stage III disease had significantly higher odds of receiving a confirmatory test vs. stage I (OR 1.5 [1.1, 2.1]). HER2 status was the largest predictor of trastuzumab use in the cohort, with HER2 equivocal, negative or unknown status patients significantly less likely to receive treatment than positive. Patients with advanced age at diagnosis (≥70y) had lower odds of trastuzumab treatment compared to younger patients (OR 0.5 [0.3, 0.7]). Increasing tumour grade was associated with higher odds of treatment. Treatment varied significantly by LHIN. **CONCLUSIONS:** Despite limitations in centrally-reported tumour pathology, we demonstrate that the use of confirmatory FISH testing in Ontario was largely consistent with Canadian guidelines. Trastuzumab use in the cohort was consistent with provincial guidelines on HER2 status in many patients, though practice varies across LHINs.

PCN159

MELODY BRAZIL - TREATMENT PATTERNS IN BRAZILIAN HEALTH CARE SYSTEM

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OBJECTIVES: To determine treatment patterns among individuals treated for unresectable stage III and IV melanoma in the Brazilian public and private health care system. **METHODS:** A retrospective chart review was conducted in patients with unresectable stage III and IV melanoma or relapsed between January 01 2008 and December 31 2009. Patients had to have at least two months follow up in 12 private