PCN117
USE OF BIOLOGICALLY BASED THERAPIES (BBTs) AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE (HRQOL) AMONG MALAYSIAN CANCER PATIENTS
Farouqi M1, Hassali AA2, Knight A1, Akmal A1, Farouqi MA2, Saleem F2, Ul Haq N2
1Universiti Teknologi MARA, Penang, Malaysia, 2Discipline of Social & Administrative Pharmacy, University of Malaya, Kuala Lumpur, Malaysia, 3School of Biomedical Sciences, Universiti Sains Malaysia, Penang, Malaysia, 4Alliance University College of Health Sciences, Penang, Malaysia, 5Universiti Sains Malaysia, Penang, Penang, Malaysia
OBJECTIVES: To examine the prevalence of biologically based therapies (BBTs) use and its impact on the quality of life (QOL) of cancer patients. METHODS: The study was undertaken with 393 cancer patients at the oncology wards of Penang General Hospital, Malaysia. The health related quality of life was measured using the European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30). RESULTS: Out of 393 participants, 184 (46.1%) reported to use different types of Complementary and Alternative Medicines (CAM). Among the CAM users, 134 (72.8%) reported using BBTs. The same 134 participants were then matched as BBTs users and non-users. No significant difference was found in Global health status/quality of life score between BBTs users and non-users (p=0.85). BBTs users and non-users. The use of biologically based therapies is common among cancer patients in Malaysia. HRQOL assessment reveals better quality of life of BBTs users than non-users. Further research is required to evaluate the potential role of BBTs in cancer care.

PCN118
A CRITICAL REVIEW OF ESA LABELING CLAIMS ON OSTEOPOROSIS: 2006-2012
Hao Y1, Evans C2
1Haus Global Market Access, Barban, NJ, USA, 2EndoPoint Outcomes, Boston, MA, USA
OBJECTIVES: To review European Medicine Agency approvals in osteoporosis for 2006-2012. To identify approved endpoints and endpoints based on patient reported outcomes (PROs). METHODS: The initial identification of endpoints was conducted through the PRO Labeling database (2006-2012). This was supplemented with a review of European Assessment Reports, Summary of Product Characteristics, Procedural Steps, Summary of the European Public Assessment Report and Scientific Discussion documents. RESULTS: There were 8 approval in osteoporosis, 3 in anemia, 4 in pain, 1 in nausea and vomiting. 1 in paroxysmal hemoglobinuria. Primary endpoints for approval of oncology drugs included progression free survival (n=5), endpoints based on pain intensity (n=3), overall survival (n=2), hemoglobinostasis/blood transfusion requirement (n=1), rescue medication (n=1), lesion clearance (n=1). The most commonly used instrument were FACT-P, FACT-G, EORTC QLQ-C30, pain NRS, nausea VAS, TQM, Trial Outcomes Index and an unreported measure. The type of PRO endpoints in the approved labeling included: Pain (n=2), nausea & vomiting (n=3), fatigue (n=3), no emesis/no use of rescue medications (n=1), treatment satisfaction (n=1). CONCLUSIONS: Manufacturers frequently supplement primary endpoints with supplemental PRO data. European approvals include labeling information that is often not permitted by the FDA such as vitamins, minerals, enzymes (n=139) and special diet such as herbs, animal products, juices (n=74) were the common type of BBTs used by patients. More than half of the participants were not sure of their monthly expenditures on BBTs. However, 26.3% reported to spend an average of 101-500 Malaysian Ringgit (MYR) per month on these therapies. Friends and family members were the most common source of BBTs recommendations (75.5%). BBTs use was disclosed to the doctors by 42.1% of the participants. BBTs users reported better HRQOL compared to non-BBTs users. On functional scale significant difference was observed in role (p=0.01) and emotional (p=0.04) scores between BBTs users and non-users. On symptom scale (n=0.006), nausea & vomiting (n=0.004), insomnia (p=0.01) and appetite loss (p=0.001) were significantly different among BBTs users and non-users. No significant difference was found in Global health status/quality of life score between BBTs users and non-users (p=0.85). The use of biologically based therapies is common among cancer patients in Malaysia. HRQOL assessment reveals better quality of life of BBTs users than non-users. Further research is required to evaluate the potential role of BBTs in cancer care.

PCN120
PATIENT REPORTED OUTCOMES IN METASTATIC CASTRATION-RESISTANT PROSTATE CANCER: A SYSTEMATIC REVIEW
Appraisal E1, Segal J, Messenger L
1University of Bath, Bath, England, Bath, MD, USA
OBJECTIVES: Patient reported outcomes (PRO) are becoming useful tools for collecting and generating evidence for new medical products to show improved quality of life (QOL) for patients with CRPC. Castration-Resistant Prostate Cancer (CRPC) is a chronic disease with high importance for patient HRQOL. The objective of this study was to review, analyze, and understand trends in the PRO instruments used in patients with CRPC. METHODS: A systematic literature search for CRPC randomized controlled trials (RCTs) with PRO endpoints was undertaken for the databases Pubmed, Embase, Biosis, Google Scholar, and Cochrane. Data was collected for the study size, interventions, year, PRO instrument, and results for PROs. Analysis was conducted to identify trends in commonly used PRO instruments and categorize results as positive, neutral or negative. RESULTS: Ten RCTs with a total of 579 participants were identified. In these studies 19 different PROs instruments were identified that were FACT-P, FACT-G, EORTC QLQ-C30, EQP25, FLCI, SDS, SUI, FDA, IPA, PROSQUI, SF-36, and QLQ-M14. The most commonly used instrument were FACT-P (used in 4,297 patients) and EQ-C-30 (used in 1,891 patients). Six studies reported positive results with improvement in quality of life symptoms (Qol) versus comparator treatments. Four studies reported results with deterioration in (QOL). Three studies reported improvements in both pain scores and global health status. Patients with CRPC have relatively longer survival and hence Qol is an important consideration for these patients. PRO instruments such as FACT-P and EQ-C-30 have been commonly used to generate evidence to show which therapies improve patient Qol.

CANCER – Health Care Use & Policy Studies

PCN121
GAPS IN US AND EU PAYER POLICIES LIMIT THEAPEUTIC OPTIONS IN PAIN CONDITIONS
Bache C1, Miller KL1, Stevens CA3
1PAREXEL Consulting, Undri, UK, 2PAREXEL Consulting, Welham, MA, USA
OBJECTIVES: Despite a shift towards consideration of pain as a focus of treatment rather than a symptom to be managed, the introduction of new products for pain has been detrimentally affected by reimbursement frameworks that are unlikely to support decisions that favour patient access. This situation exists despite public support for effective pain management, particularly within the palliative care setting. This study aims to identify the mechanisms that limit the available therapeutic options in pain management and to suggest potential alternative approaches to be considered. METHODS: The study involved interviews with 30 interviewees in the US, France, Germany and the UK, including national level HTA influencers, medical directors, influencers on hospital formularies and product use, palliative medicine consultants, anesthesiologists and oncologists. Interviews focused on the challenges of securing favourable reimbursement, reimbursement policy in the US and EU, including in instances where the product has a recognised clinical benefit. RESULTS: New pain products struggle to secure uptake in both the US and EU. Countries adopting a model that attaches the achievable price level with reimbursement policy in the US and EU, including in instances where the product has a recognised clinical benefit. The absence of life extension and common existence of pain in late stage disease means countries adopting a cost-effectiveness model (UK) are methodologically unsuited to evaluation of such products. US payers are likely to place restrictive prior authorisation requirements on products while cheap options exist. CONCLUSIONS: Patient access to new pain therapies is significantly limited by reimbursement policy in the US and EU, including in instances where the product has a recognised clinical benefit.

PCN122
PREVALENCE, DIAGNOSIS & TREATMENT PROTOCOLS FOR BREAST CANCER IN SOUTHERN PUNJAB
Ahmed MD1, Khan MS1, Usman Minhaj M1
1The Islamia University of Bahauwalpur, Bahauwalpur, Pakistan, 2The Islamia University of Bahauwalpur, Punjab-Pakistan, Bahauwalpur, Pakistan
OBJECTIVES: To explore the prevalence, diagnosis & treatment protocol of breast cancer in patients treated at Bahauwalpur institute of nuclear medicine and oncology (BINNO). METHODS: A retrospective study was carried out on the data from the treatment records of patients (n=300). Patient age, education status, included breast, type & stage of disease at diagnosis, socioeconomic status of patient and metastasis in patients as well as the treatment protocol was evaluated. Statistical tools were applied for analysis. RESULTS: The mean age of patients was 48±5% & 92% patients were illiterate. Infiltrating ductal carcinoma (IDC) 96% was the most common type of breast cancer found in population and were mostly diagnosed at Grade 3 (69%). Most of the patient had carcinoma of spiritual needs. CONCLUSIONS: These findings provide insight into the cultural dimension inherent in the caregiving experience and perceptions of QOL of MA family caregivers. It is imperative to recognize the influence of culture in developing culturally relevant interventions specifically designed to reduce the burden of cancer and improve overall caregiver QOL.
right breast (53%) while about 43% had of left breast. Patients with breast cancer were mostly married (99%) & patients were belonging to poor socioeconomic status. Diagnosis for all patients were confirmed for the cancer patients were mammography, biopsy, USG, X-ray & MUGA & bone scan and about 60% of the population had undergone mastectomy. CONCLUSIONS: Infiltrating ductal carcinoma (96%) was found the most common type of breast cancer in southern Punjab. The reported tumor status of the patients might affect the prevalence of breast cancer in patients

PCN123
THE USE OF COMPLEMENTARY AND ALTERNATIVE MEDICINES (CAM) AMONG PATIENTS WITH CANCER: A DESCRIPTIVE STUDY
Farooqui M1, Hassali AA2, Shattar AK3, Shafie AA3, Farooqui MA4, Saleem F3, Ul Haq M5
1University of Technology MARA, Penang, Malaysia, 2Discipline of External Affairs Pharmacy, Universiti Sains Malaysia, Pinang, Pulau Pinang, Malaysia, 3Universiti Sains Malaysia, Penang, Malaysia, 4Universiti Teknologi MARA, Penang, Malaysia, 5Discipline of External Affairs Pharmacy, Universiti Sains Malaysia, Pinang, Pulau Pinang, Malaysia, 6Alliance University College Of Medical Sciences, Penang, Malaysia, 7Universiti Sains Malaysia, Penang, Malaysia.

OBJECTIVES: To evaluate the prevalence and patterns of CAM use among cancer patients in Malaysia. In addition, the study focuses on the perceived effectiveness of CAM over conventional therapies, information seeking and CAM disclosure to health care providers. METHODS: The study was designed as a questionnaire based, cross sectional analysis. A prevalence based sample of 393 cancer patients attending the oncology clinics at Penang General Hospital was hereby selected for the study. Adult patients (18 years old), having diagnosed with cancer (any type), able to read or understand Malay (national language of Malaysia) or English language were recruited between August to November 2011. RESULTS: Overall, 393 questionnaires were completed and included in the analysis, showing that 46% of cancer patients had used CAM, with most (57.6%) believing that CAM therapies assisted the body’s natural forces to heal. CAM usage was significantly associated with gender (P=0.021), level of education (P<0.001), employment status (P=0.02) and monthly income (P=0.001). Among the frequently used CAM were biologically-based therapies including nutritional supplements (used by 75.5% of the participants). Friends and family members were the most common source of CAM information (for 75.4% of the patients). Only 13% reported side effects from using CAM. CAM use disclosure to the doctors was 43%; however, doctors had specifically asked about CAM use in 33.4% of the cases. The most common reason given for non-disclosure was not important for the doctors to know about CAM use (34.2%). CONCLUSIONS: Cancer management and treatment requires compliance to effective therapies at early stages. Health care providers should engage cancer patients in an open non-judgmental dialogue to ascertain better understanding of cancer and its treatment options.

PCN124
INDIVIDUAL RISK PROFILING FOR BREAST CANCER RECURRENCE: TOWARDS TAILORED FOLLOW-UP SCHEMES
Krausen J1, Vliegen I1, Siesling S2, Kraase J3, Bierman JM4
1University of Twente, Enschede, The Netherlands, 2Medical Spectrum Twente Hospital, Enschede, The Netherlands.

OBJECTIVES: Current international guidelines for breast cancer follow-up are not specific to individual risk of local regional recurrences. Instead, for personalised behaviour and CAM disclosure to health care providers. METHODS: The study was designed as a questionnaire based, cross sectional analysis. A prevalence based sample of 393 cancer patients attending the oncology clinics at Penang General Hospital was hereby selected for the study. Adult patients (18 years old), having diagnosed with cancer (any type), able to read or understand Malay (national language of Malaysia) or English language were recruited between August to November 2011. RESULTS: Overall, 393 questionnaires were completed and included in the analysis, showing that 46% of cancer patients had used CAM, with most (57.6%) believing that CAM therapies assisted the body’s natural forces to heal. CAM usage was significantly associated with gender (P=0.021), level of education (P<0.001), employment status (P=0.02) and monthly income (P=0.001). Among the frequently used CAM were biologically-based therapies including nutritional supplements (used by 75.5% of the participants). Friends and family members were the most common source of CAM information (for 75.4% of the patients). Only 13% reported side effects from using CAM. CAM use disclosure to the doctors was 43%; however, doctors had specifically asked about CAM use in 33.4% of the cases. The most common reason given for non-disclosure was not important for the doctors to know about CAM use (34.2%). CONCLUSIONS: Cancer management and treatment requires compliance to effective therapies at early stages. Health care providers should engage cancer patients in an open non-judgmental dialogue to ascertain better understanding of cancer and its treatment options.

PCN125
QUANTIFICATION OF BENEFITS AND RISKS IN MEDICAL IMAGING TESTING: A LITERATURE REVIEW
Agapito M, Devine B, Bresnahan BW, Garrison L1
1University of Washington, Seattle, WA, USA, 2University of Washington, Seattle , WA, USA, 3University of Washington, Seattle, WA, USA

OBJECTIVES: Appropriate use of medical imaging tests is a growing area of policy discussion. Quantitative methods can characterize benefits and risks of medical imaging tests and distinguish necessary from unnecessary utilization. Our objective was to review the extent of quantitative benefit-risk analysis (QBARA) published in medical imaging testing. METHODS: Using PubMed and the Cochrane Library, a computerized search was performed to identify studies published from January, 1979 and January, 2013. The search was limited to include only studies that quantified benefits and risks/harms of imaging radiation imaging in screening or diagnostics. RESULTS: Seventy-eight studies called for the need to weigh benefits and risks associated with medical imaging testing, however, only seven benefited and risked one risk factor. Of these, two studies reported BRA of mammography. Three studies addressed positron emission tomography (PET): two studies assessed BRA of full body PET in cancer screening and one study assessed BRA of PET in lung cancer diagnosis. The remaining studies reported BRA of computed tomography (CT) and SPECT. Of the four studies published in English, benefits were reported in terms of life extension, and harms were reported as radiation-related cancer risk of 0.04% per year. Studies used micro-simulation modeling, epidemiological or survey methods. CONCLUSIONS: This review illustrates that a gap exists between the number of studies referring to the need for assessing the benefit-risk balance in medical imaging and the number of studies measuring that balance. Challenges such as translating imaging information into impacts on patient outcomes, multiple applications of imaging tests, difficulty in measuring harms from ionizing radiation and additional procedures spurred the positive/negative result under the necessary movement toward using quantitative methods. Meeting the goals of patient-centered outcomes and understanding areas of appropriate use, overutilization and underutilization requires further development of a framework for quantitative BRA of medical imaging tests.

PCN126
WHICH IS MORE VALUABLE, LONGER SURVIVAL OR BETTER QUALITY OF LIFE? ISRAELI ONCOLOGISTS’ AND FAMILY PHYSICIANS’ ATTITUDES TOWARD THE RELATIVE VALUE OF NEW CANCER AND CONGESTIVE HEART FAILURE INTERVENTIONS
Greengarden M, Hamnerman A, Vinker S, Shani A, Yermiyahu Y, Neumann P1
1Ben Gurion University of the Negev, Beer-Sheva, Israel, 2Clalit Health Services, Tel-Aviv, Israel, 3Sheba Medical Center, Tel-Hashomer, Israel, 4Tufis Medical Center, Boston, MA, USA

OBJECTIVES: To compare Israeli oncologists’ and family physicians’ value preferences for life-prolonging vs. QoL enhancing outcomes attributable to cancer and congestive heart failure (CHF) interventions. METHODS: We presented physicians with two scenarios involving a hypothetical patient with metastatic cancer expected to survive 12-months with current treatment. In a life-prolongation scenario, we suggested that a new treatment increases survival at an incremental cost of $50,000 over the standard of care. Participants were asked what minimum improvement in median months of survival the new therapy would need to provide in order to recommend it over standard of care. In the QoL-improving scenario, we asked the maximum WTP for an intervention that leads to the same survival as the standard treatment, but increases patient’s QoL from 50 to 75 (on a 100-scale). RESULTS: In the life-prolongation scenario the median cost-effectiveness threshold implied by oncologists was $150,000/QALY and $100,000/QALY for cancer and CHF respectively. Median cost-effectiveness thresholds implied by family physicians were $50,000/QALY regardless the disease type. WTP for the QoL-enhancing scenario was $150,000/QALY and did not differ by physicians’ specialty or disease type. CONCLUSIONS: Our findings suggest that family physicians value life-prolonging and QoL-enhancing interventions roughly equally, while oncologists value interventions that extend survival more highly than those that only improve QoL. These findings may have important implications for coverage and reimbursement decisions of new technologies.

PCN127
CANCER DRUG PRICING TRENDS IN THE UNITED STATES AND THE UNITED KINGDOM (2011-2013)
Agarwal S, Topaloglu H, Kumar S

OBJECTIVES: To understand relative price differential for cancer drugs in the U.S. and the U.K. Develop implications for pricing strategy and patient access for oncology products. METHODS: Ten branded cancer drugs were selected and their prices for similar dose and packaging were compared in the U.S. and the U.K. Prices were analyzed for the end of 2011 and 2012. Historical exchange rates were used to convert British pounds to US dollars. Relative price discount was calculated for all selected cancer drugs. KOLs and payers were interviewed to better understand current and future implications of this price differential. RESULTS: The median price discount for selected ten branded cancer drugs in the UK versus the United States was -50%. The range of discount for 10 branded cancer drugs was 27%-61%. The price discount for oral small molecule drugs was higher than for biologics (55% vs. 45%). Since the U.K. is one of the few remaining free pricing markets in Europe, other European markets are likely to have even higher discount compared to the U.S. Due to the pricing market similarity, U.S. cancer patients bear significantly higher costs than patients in the UK. KOL and payer interviews suggest U.S. pricing trends for cancer drugs are unlikely to be sustained in the future. Objective price increases for similar dose and packaging are significantly higher than the prices in the U.S. This price differential is unlikely to be sustained in the future.

PCN128
A COMPARISON OF MEDICAL COMPUTED TOMOGRAPHIC UTILIZATION AND POTENTIAL RELATED CANCER RISKS IN THE UNITED STATES AND IN CANADA (1975-2005)
Bigner D, Deutsch A1
1McGill University, Montreal, QC, Canada, 2Zovaril Consulting Inc, Westmount, QC, Canada

CONCLUSIONS: Infiltrating ductal carcinoma (96%) was found the most common type of breast cancer in southern Punjab. The reported tumor status of the patients might affect the prevalence of breast cancer in patients.