

pleted the EQ-5D-5L. Inclusion criteria were current chronic phase of CML, visits after June 2012, and age  $\geq 18$  years at diagnosis. The analysis included descriptive statistics of the sample population and derivation of a utility value for each patient. Kruskal Wallis test was conducted to compare the utility values for non-parametric data, and t test was conducted for parametric data. A utility value of 0 implies death, while a value of 1 implies full health. **RESULTS:** Out of the 81 questionnaires that were mailed 33 (40.7%) were returned. Three returned questionnaires were excluded due to failure to complete the instrument, and one patient passed away. Of the 29 patients in the final sample, there are 15 males, the mean age was 54.3 $\pm$ 15.0 years, the mean utility was 0.79 $\pm$ 0.15, and the mean duration of CML was 5.1 $\pm$ 3.6 years. For current CML treatments, 3 patients had undergone stem cell transplantation (SCT), 25 patients were receiving tyrosine kinase inhibitors (TKIs), and one patient discontinued medication due to adverse events. Overall, the mean utility difference between SCT and TKIs was not statistically significant (0.72 $\pm$  0.15 vs. 0.80  $\pm$  0.15,  $p=0.35$ ). Among TKIs, Imatinib had the highest utility scores (0.88 $\pm$ 0.14,  $n=10$ ), followed by ponatinib (0.83 $\pm$ 0.15,  $n=3$ ), nilotinib (0.81 $\pm$ 0.04,  $n=3$ ), dasatinib (0.72 $\pm$ 0.12,  $n=8$ ), and bosutinib (0.48,  $n=1$ ). There was no statistical difference in utilities in patients who received one line of treatment (0.83 $\pm$ 0.15,  $n=13$ ) vs. multiple lines (0.76 $\pm$ 0.15,  $n=12$ ,  $p=0.22$ ). **CONCLUSIONS:** Although the study population was small, our results indicate that current US CML patients have good QoL scores. A larger sample size is needed for further research.

#### PCN143

##### SANDOSTATIN LAR PATIENT JOURNEY

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**OBJECTIVES:** Carcinoid tumors are a type of neuroendocrine tumor (NET), most often occurring in the gastrointestinal tract. These tumours are rare and difficult to identify, since symptoms are often associated with other conditions. Once correctly diagnosed, many symptomatic patients are treated with Sandostatin LAR. This study sought to identify the typical NET patient journey, from onset of symptoms to diagnosis and treatment. **METHODS:** 75 NET patients that are currently treated with Sandostatin LAR were interviewed by telephone using a 30-minute structured questionnaire comprised of a mix of closed-ended and open-ended questions. **RESULTS:** More than three quarters (76%,  $n=57$ ) of patients presented with symptoms prior to NET diagnosis. 74% of these symptomatic patients ( $n=42$ ) were first seen by a general practitioner / family doctor. However NET was recognised within 1 year in only 51% of cases ( $n=29$ ), while in the remaining 49% of cases it took more than a year to correctly diagnose NET. Out of all asymptomatic patients ( $n=18$ ), in 39% cases (7/18\*100%,  $n=7$ ) the tumors were found incidentally while the patient was undergoing treatment for another condition, while in 33% cases (6/18\*100%;  $n=6$ ) NET condition was discovered due to abnormal test results. Two-fifths (43%,  $n=32$ ) of respondents were misdiagnosed prior to receiving NET diagnosis, with 53% ( $n=17$ ) of misdiagnosed cases persisting for more than 1 year. Overall, 83% of the sample saw 2 or more physicians before NET was diagnosed. **CONCLUSIONS:** The results of this research indicate that Canadian patients can experience significant delays in the correct diagnosis and appropriate treatment of NET. This is attributable in part to the nonspecific nature of the signs and symptoms of NET, but also due to a lack of awareness of NET among frontline physicians and the general public.

#### PCN144

##### RELATIVE INFLUENCE OF FACTORS DETERMINING A WOMAN'S PREFERENCE FOR TREATMENT OPTIONS IN OVARIAN CANCER: A DISCRETE CHOICE EXPERIMENT

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**OBJECTIVES:** To examine relative preferences for symptoms, treatment-related side-effects and progression-free survival (PFS) in women with ovarian cancer using a discrete choice experiment (DCE). **METHODS:** A pilot study was conducted of women with advanced or recurrent ovarian cancer. In the DCE, participants were asked to choose between two treatment scenarios, modeled on characteristics of standard intravenous (IV) and intraperitoneal/intravenous (IP/IV) treatments for newly diagnosed ovarian cancer. Each scenario included 7 attributes with 2-3 levels each: mode of administration (IV versus IP/IV); visit frequency (one per week, two per 3 weeks, one per 3 weeks); treatment-related abdominal symptoms, neuropathy, fatigue, nausea, and vomiting; and PFS (15, 18, 21 and 24 months). We used a balanced overlap design with 10 versions of the survey. Each participant evaluated 12 random choice and one fixed-choice scenario. Mixed logit regression modeled participant's choices as a function of attribute levels. **RESULTS:** 95 women completed the survey. Mean age was 57 and 81% were Caucasian. Half (47%) had experienced disease recurrence and 49% were currently receiving chemotherapy. Compared to scenarios with 15 months of PFS, the relative odds that a participant would choose a scenario with 18, 21 and 24 months of PFS were 1.5 ( $p=0.01$ ), 3.4 ( $p<0.001$ ) and 7.5 ( $p<0.001$ ), respectively. Assuming a linear relationship with PFS, on average, patients were willing to tradeoff 6.7 months of PFS for an improvement from severe to mild nausea and vomiting during treatment, 5.0 months of PFS for an improvement from severe to mild neuropathy, and 3.7 months of PFS for an improvement from severe to moderate abdominal symptoms. **CONCLUSIONS:** Progression-free survival time is the most important factor in determining preferences for chemotherapy regimens. However, women with ovarian cancer were willing to give up significant amounts of PFS time for marked reductions in the severity of treatment-related side effects.

#### PCN145

##### PHYSICIANS' PREFERENCES FOR BONE METASTASES TREATMENTS IN CANADA

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**OBJECTIVES:** Among the bone-targeted agents (BTAs) currently approved for the prevention of skeletal-related events (SREs), several characteristics may be considered by physicians when making treatment decisions. This study evaluated Canadian physicians' treatment preferences for BTAs used to prevent SREs in patients with bone metastases from solid tumors. **METHODS:** Physicians treating patients with bone metastases from solid tumors completed a web-enabled discrete-choice experiment survey consisting of 10 choices between pairs of hypothetical medication profiles for patient with either breast or prostate cancer. Each hypothetical medication profile included five attributes within a pre-defined range (primarily based on prescribing information): months until first SRE (10, 18 and 28 months); months until worsening of pain (3, 6 and 10 months); annual risk of osteonecrosis of the jaw (ONJ; 0%, 1% and 5%); annual risk of renal impairment (0%, 4% and 10%); and mode of administration (oral tablet, subcutaneous injection, 15-minute infusion and 120-minute infusion). Choice questions were based on an experimental design with known statistical properties. The survey was pretested with 8 physicians using open-ended interviews. A main-effects random parameters logit model was used to analyze the data. **RESULTS:** A total of 200 Canadian physicians completed the survey. Over the attribute levels included, months until first SRE, the risk of renal impairment, and months until worsening of pain were the most important attributes. For those attributes, better levels (outcomes) were significantly preferred to worse levels ( $P < 0.05$ ). For mode of administration, subcutaneous injection was preferred over infusion regardless of duration ( $P < 0.05$ ). **CONCLUSIONS:** When making treatment decisions regarding choice of BTA for patients with bone metastases, delaying the onset of SREs and managing the risk of renal impairment are the primary considerations for Canadian physicians. Also, respondents had well-defined preferences for subcutaneous injections over infusion every 4 weeks.

#### PCN146

##### QUALITATIVE ASSESSMENT OF MULTIPLE MYELOMA SYMPTOMS AND HEALTH-RELATED QUALITY OF LIFE IN RELAPSED/REFRACTORY PATIENTS AND COMPARISON TO THE EORTC QLQ-C30 AND MY-20, FACT-MM, AND MDASI-MM Task PC<sup>1</sup>, Taylor F<sup>2</sup>, Shields A<sup>3</sup>, Mehta J<sup>1</sup>, Foley C<sup>2</sup>, Olude O<sup>2</sup>, Lamoureux R<sup>2</sup>, Iovin R<sup>2</sup>, Hsu K<sup>1</sup>

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**OBJECTIVES:** It is unclear whether the conceptual coverages of the instruments available to evaluate the health-related quality of life (HRQoL) of multiple myeloma (MM) patients are adequate in the relapsed or refractory (R/R) setting, with respect to the FDA's patient-reported outcome (PRO) guidance. To address this uncertainty, we conducted qualitative interviews with R/R MM patients and compared the results to the conceptual frameworks of three existing instruments. **METHODS:** Two consecutive sets ( $n=15$  and  $n=8$ ) of qualitative concept elicitation (CE) interviews were conducted with R/R MM patients in the U.S. The concepts reported were compared with the conceptual frameworks of the EORTC QLQ-C30 and QLQ-MY20, FACT-MM, and MDASI-MM. In addition, a conceptual model was devised based on the results of these interviews, and an analysis of the relative timing (with respect to treatment/disease course) of the reported symptoms and impacts was conducted. **RESULTS:** A total of 23 R/R MM patients (age range=50 to 89 years; mean age=66.7 $\pm$ 10.1 years; male=56.5%) participated in the CE interviews. A total of 37 symptom concepts and 55 HRQoL impacts were reported. Of the six symptom concepts reported by >2 patients, five (83.3%) were covered by the QLQ-C30 and MY-20, three (50.0%) by the FACT-MM, and three (50.0%) by the MDASI-MM. Of the 23 impacts reported by >2 patients, 14 (60.9%) were covered by the QLQ-C30 and MY-20, 9 (39.1%) by the FACT-MM, and 7 (30.4%) by the MDASI-MM. Analysis of the timing of symptom/impact reporting revealed that the majority of concepts noted by >2 MM patients were present both pre- and post-relapse. **CONCLUSIONS:** These findings indicate that the EORTC QLQ-C30 and QLQ-MY20 instruments are appropriate for capturing the symptom and impact domains most often reported by R/R MM patients, although room may remain for improvement in assessing functional impacts at the conceptual level in this population.

#### PCN147

##### RECRUITING AND INTERVIEWING NON-METASTATIC CASTRATION-RESISTANT PROSTATE CANCER PATIENTS FOR QUALITATIVE STUDY PARTICIPATION VIA AN INTERNET-BASED DIGITAL PATIENT COMMUNITY

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**OBJECTIVES:** To perform a qualitative patient interview study using an internet-based digital patient platform for recruitment and telephone and webcam for interviews. **METHODS:** To design the qualitative study we followed the steps outlined in the ISPOR PRO Good Research Practices Task Force Report: Part 1 (Patrick et al, 2011). Briefly, a qualitative interview guide was developed and approved by IRB. Participants were recruited, consented, enrolled, and interviewed online. Each interview was audio recorded and transcribed. Analysis of the qualitative data was performed by experienced market researchers. **RESULTS:** Screening, demographic, and medical information was gathered directly from patients online, via the internet, with no interaction from the patient's physician(s) or site. Existing members of MediGuard, an online free medication monitoring service, were sent an email invitation to participate in the study. Members who choose to click on the link were directed to a website where they accessed information regarding the study, provided consent to participate, self-screened for eligibility, and reported baseline characteristics. Consented participants were contacted via phone to schedule a time to participate in an individual interview via telephone or webcam. Interviews were audio recorded, and lasted 60-75 minutes. 17 patients were interviewed. **CONCLUSIONS:** Recruiting and interviewing patients via the internet and phone is a feasible, faster, and potentially lower cost alternative to face to face interviews. Some benefits of direct to patient research include potential to reduce patient travel burden to a study

site and access to patients who are home bound or located in remote geographic locations. This novel approach did not seem to alter the participant's ability to participate in a qualitative study.

#### PCN148

##### IDENTIFYING SYMPTOMS AND IMPACTS EXPERIENCED BY MEN WITH NON-METASTATIC CASTRATION RESISTANT PROSTATE CANCER

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**OBJECTIVES:** We sought to identify the most relevant and important symptoms and impacts of non metastatic (M0) castration resistant prostate cancer (CRPC) from the patient's perspective. **METHODS:** First, a literature review was performed that focused on symptoms related to living with M0 CRPC. Then, individual interviews with five clinicians experienced in treating PC were conducted to understand the clinical perspective of treating M0 CRPC. Finally, individual interviews with 17 M0 CRPC patients were conducted following a semi-structured interview guide. Patients were asked about symptoms, impacts of living with M0 CRPC, and interference of symptoms with daily living and impacts on a scale of 0-10. **RESULTS:** 35 unique symptoms were mentioned by patients: 15 patients mentioned erectile issues, 13 loss of sexual desire, 11 urge to urinate, and 11 incontinence. No patient rated the interference of symptoms higher than a six on the impact scale. The most common impacts mentioned included: need to plan for urinary frequency (n=9), interference with daily activities (n=8), and anxiety (n=7) or frustration (n=7) over the diagnosis, symptoms, or treatment. Clinicians confirmed the symptoms expressed by patients and noted that many could be attributed to prior and/or current treatments for PC and not the PC itself, a finding observed consistently in the published literature. **CONCLUSIONS:** The most relevant and important symptoms (erectile dysfunction, urinary symptoms, anxiety, and emotional impacts) expressed by patients aligned with those mentioned by clinicians and the literature. This data provides valuable insight into patients' experience with M0 CRPC illustrating that the most relevant symptoms and impacts thereof expressed by patients may be attributed to PC therapy and not to the consequences of the M0 CRPC disease state itself.

#### PCN149

##### ASSESSMENT OF RESPONSE SHIFT AND TRUE CHANGE USING STRUCTURAL EQUATION MODELING FOR HEALTH-RELATED QUALITY-OF-LIFE SCORES IN PATIENTS WITH BREAST CANCER AFTER SURGERY

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**OBJECTIVES:** Response shift can be considered measurement bias in the assessment of HRQOL. The purpose of this study was to detect response shifts and true change in health-related quality-of-life (HRQOL) scores in patients with breast cancer after surgery using structural equation modeling (SEM) proposed by Oort F. J. **METHODS:** The HRQOL data set was derived from published in the 'Breast Cancer Res Treat' in 2011 to reveal predictors of HRQOL scores 1 and 2 years after breast cancer surgery. HRQOL was assessed in patients with breast cancer (N=196) using the Functional Assessment of Cancer Therapy - General (FACT-G) at baseline (1 month), 6, 12, and 24 months after surgery. We developed models using 'four domains' (physical well-being [PWB], social/family well-being [SWB], emotional well-being [EWB], and functional well-being [FWB]) subscales of the FACT-G) and 'higher concept' integrating four domains. Analyses were performed using Oort's SEM (Software: IBM SPSS AMOS 20.0) approach to detect response shifts and true change. **RESULTS:** The following response shifts were detected: between baseline and 6 months, uniform recalibration and reprioritization in SWB and non-uniform recalibration in PWB; and between baseline and 12 months, uniform/non-uniform recalibration and reprioritization in SWB. True change was detected both between baseline and 6 months and between baseline and 12 months for overall QOL. **CONCLUSIONS:** The analyses using the models developed in this study based on 'four domains' and 'higher concept' yielded more easily interpretable results compared to previously reported models based on 'items' and 'domains'. The results of this study will help understand possible measurement bias due to response shift effects on the assessment of HRQOL in a longitudinal study.

#### PCN150

##### DESIGN AND VALIDATION OF A QUESTIONNAIRE FOR MEASURING PERCEIVED RISK OF SKIN CANCER

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**OBJECTIVES:** The aim of this study was to design and validate a self-administered questionnaire for measuring the perceived risk of skin cancer. **METHODS:** A self-administered questionnaire with a visual Likert-type scale was designed based on the results of the analysis of the content of a survey performed in 100 patients in the Dr.Ladislao de la Pascua Skin Clinic, Distrito Federal México, Mexico. Subsequently, the questionnaire was administered to a sample of 359 adult patients who attended the clinic for the first time. As no gold standard exists for measuring the perceived risk of skin cancer, the construct was validated through factor analysis. **RESULTS:** The final questionnaire had 18 items. The internal consistency measured with Cronbach alpha was 0.824 overall. In the factor analysis, 4 factors (denoted as affective, behavioral, severity, and susceptibility) and an indicator of risk accounted for 65.133% of the variance. **CONCLUSIONS:** The psychometric properties of the scale were appropriate for measuring the perception of risk in adult patients (aged 18 years or more) who attended the dermatology clinic. This is the first questionnaire in Spanish to measure perceived risk of skin cancer that serves to quantify the response to interventions for preventing this disease.

#### PCN151

##### PATIENT REPORTED OUTCOMES IN CASTRATION-RESISTANT PROSTATE CANCER

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**OBJECTIVES:** Patient reported outcomes (PRO) are becoming useful tools for collecting and generating evidence for new medical products to show improvements in health-related quality of life (HRQoL). 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 PROs 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 5,797 patients were identified. In these studies there were thirteen different PROs instruments were identified that were FACT-P, FACT-G, BPI-SF, EQC30, EQPR25, FLIC, SDS, SUF, PDA, IPDA, PROSQOLI, SF-36, and QOLM-P14. The most commonly used instrument were FACT-P (used in 4,297 patients) and EQC-30 (used in 1,091 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 improvement in pain scores. **CONCLUSIONS:** Patients with CRPC have relatively longer survival and hence QoL is an important consideration for these patients. PRO instruments such as FACT-P and EQC-30 have been commonly used to generate evidence to show which therapies improve patient QoL.

#### PCN152

##### IMPACT OF COLORECTAL CANCER ON ACTIVITIES OF DAILY LIVING AND DEPRESSION RISK AMONG OLDER AMERICANS

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**OBJECTIVES:** 1) Estimate change in activities of daily living (ADL) and risk for major depressive disorder (MDD) among older Americans >64 years following diagnosis and treatment of colorectal cancer (CRC); 2) Compare change in ADL function and MDD risk among CRC patients to matched controls without cancer. **METHODS:** This population-based study used the Surveillance, Epidemiology, and End Results-Medicare Health Outcomes Survey (SEER-MHOS) dataset (1998-2007). Medicare managed care beneficiaries diagnosed with CRC between completion of baseline and follow-up MHOS (n=349) were matched to non-cancer controls (n=1,745) using propensity scores. Analysis of covariance models estimated change in ability to perform six ADLs: bathing, dressing, eating, getting in or out of chairs, walking, using the toilet. Logistic regression was used to estimate MDD risk. Covariates included socio-demographic, clinical and survey characteristics. **RESULTS:** Mean time from diagnosis to MHOS follow-up was 12.3 months (SD 9.8) for CRC patients (n=103 Stage I, 122 Stage II, 95 Stage III, 29 Stage IV). Though patients and controls reported similar ADL impairment at baseline (.97 vs. .92; p=0.06), CRC patients had greater impairment at follow-up (mean 2.21 vs. .92; p<0.01). Mean increase in ADL impairment was 1.02 for Stage I, 1.25 for Stage II, 1.53 for Stage III, and 1.67 for Stage IV patients (each p<0.01). Compared to controls, CRC patients suffered greater impairment with respect to bathing (p=0.01), getting in/out of chairs (p=0.01) and walking (p<0.01). CRC patients and controls had similar MDD risk at baseline (odds ratio [OR] 1.22 [95% confidence interval .94-1.58]) and at follow-up (OR 3.18 [0.65-15.69]). **CONCLUSIONS:** CRC has adverse effects on ADL functioning among older Americans—even in the early, curable stages. This study informs clinicians and caregivers of the need to identify opportunities to provide supportive care for patients' basic needs of self-care.

#### PCN154

##### THE REAL IMPACT OF QUALITY OF LIFE (QOL) ENDPOINTS ON MARKET ACCESS DECISIONS ACROSS MARKETS - A CASE STUDY OF ONCOLOGY PRODUCTS

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**OBJECTIVES:** Recent approvals of targeted oncology therapies have resulted in increased patient survival, and potential comorbidities. Subsequently, a greater emphasis has been placed on QoL and PRO endpoints. However, the impact of QoL instruments on market access of new oncology products remains unclear. This research aims at understanding the true relevance of QoL endpoints in payer decision making. **METHODS:** The research was conducted through in-depth secondary research and interviews with payers in 6 countries including the US, Germany, France, Spain, Italy, and Sweden. **RESULTS:** In the markets studied, QoL data is a requirement to be submitted for reimbursement; however, it is not a key determinant of reimbursement or pricing decisions at a national level. Some countries like Italy and Spain view QoL data as being important at a regional and local level for inclusion in formularies and guidelines. Furthermore, payers suggest that QoL is considered only in a qualitative sense based on the safety profile of a drug, and do not consider the instruments used to measure it. For example, in France, although the expectation is that a disease-specific QoL instrument is submitted for review by the Transparency Commission, this data will not contribute towards an ASMR determination. Meanwhile, in Sweden, the TLV requires the use of only generic instruments such as EQ-5D that are validated to be used in cost/QALY calculations, unlike disease specific instruments. **CONCLUSIONS:** Contrary to the increasing academic interest in QoL and PRO endpoints, these have not yet translated into playing a significant role in payer decision making for new oncology products. Currently, QoL instruments are used in oncology clinical trials as standard protocol. However, differentiating one drug over another through an improvement demonstrated using QoL instruments does not yet directly translate to an advantage from a market access point of view for that drug.