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 DrLadislao 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. Fours 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.