PCN129  
EVALUATION OF HEALTH-RELATED QUALITY-OF-LIFE CONCEPTS ASSOCIATED WITH TRIPLE-NEGATIVE BREAST CANCER  
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OBJECTIVES: Our aim was to develop a conceptual framework in patients with locally recurrent or metastatic triple-negative breast cancer (TNBC) through a literature review and patient interviews. METHODS: A literature review on health-related quality of life (HRQoL) in advanced breast cancer was performed using the EMBASE database. Clinical experts were asked to identify key HRQoL concepts related to TNBC. These concepts were then used to conduct semi-structured individual interviews with patients with TNBC in the UK and France until saturation of concepts was reached. Patients were asked to cite important concepts related to the impact of disease on HRQoL and to rate them. Following IFGQR guidelines, qualitative analysis was used to identify salient disease and treatment impact. RESULTS: Two clinical experts and 28 patients were interviewed (age range, 26–83 years). Twenty-one patients (70%) had metastatic disease and 7 (25%) had locally recurrent disease. Results of the patient interviews indicate that TNBC affects multiple dimensions of HRQoL. Psychological functioning (shame/embarrassment, anger, worry, depression), role functioning (work limitation, social/leisure activities), energy levels, daily living and physical dimensions. Patients experienced distress because of fear of death, fear of disease progression, a changed body image, and concern about their loved ones. Patients associated a greater decrease in HRQoL with chemotherapy compared to radiotherapy and surgery as it resulted in a large range of impairments that impacted all relevant life domains: psychological and physical health, participation in social and occupational activities, and functioning in daily living. Coping strategies were included in the interviews. All patients prioritized the impact of disease differently. CONCLUSIONS: TNBC and its treatment have a profound effect on all aspects of patients’ lives. Results of this study were used to inform the inclusion of patient-reported outcome measures in phase 3 clinical development.

PCN130  
INvariance of quality of life questionnaire EORCT QLC-Q30 in different cancer indications  
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OBJECTIVES: To validate the short version of the QLQ-C30 obtained for patients with non-small-cell lung cancer in patients with head and neck, prostate, breast or cervix cancer. METHODS: We analyzed data of 636 patients distributed: 237 diagnosed with head and neck cancer, 146 diagnosed with breast cancer, 140 diagnosed with cervix cancer and 113 diagnosed with prostate cancer. The analysis followed a 4-step approach. First, we conducted a Mokken nonparametric item response analysis to ascertain the QLQ-C30 dimensionality and separate several scale if appropriate. Second, we conducted a parametric Samejima’s graded response model (GRM) to assess the item characteristics and information for each scale. Third, we did a confirmatory factor analysis (CFA) to test the scales unidimensionality and to obtain standardized factor loadings to suggest a reduced version of the QLCQ. Finally, we assessed the discriminative validity of the reduced version by using receiver-operator curve (ROC) analysis. RESULTS: In this study the reduction of the generalized Cancer Module (GCM) to 6 items and the reduction of the 6 scores and the reduction of the 6 scores account for a 63.8% of the overall variability. Furthermore, it was found that 6 score explained 62.3% of the variability in patients with head and neck cancer. CONCLUSIONS: The short form of the QLC-Q30 is reliable and valid in patients with non-small-cell lung cancer, head and neck cancer, breast cancer, cervix cancer and prostate cancer.

PCN131  
PATIENTS’ GROUPS AND ADVOCACY IN ONCOLOGY: AWARENESS, SUPPORT AND DECISION-MAKING IN CANCER CARE  
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OBJECTIVES: Patients’ groups and advocacy play an important role in the oncology sector. They are important actors in the oncologic patient pathway, however, no systematic data about their role in decision-making about cancer patient needs. Our objective was to identify and describe the main needs of cancer patients in Brazil. METHODS: We analyzed the PAP program database from 01/2013 to 08/2014. This is a support and personalized counseling program dedicated to cancer patients and their families. A literature review on health-related nonprofit institution. We retrieved and described the applicants’ profiles (patient, family, specialty society, physicians, etc) and type of required information (patient rights, reimbursement quality-of-life or access to companion diagnostic or treatment procedures). RESULTS: In the aforementioned period, 2,214 applicants received 5,586 orientations (1,683 by telephone and 903 by electronic mail). Forty-nine percent of the requests were made by the patients themselves or by a family member and 2% by health care professionals. Among all requests, 77% were regarding patient’s rights and 23% were questions on health information. The 1,640 requests on patient rights were divided as follows: social rights (62%), problems related to access to treatments (10%) (6%), problems on professional medical practice (3%), and psychological (3%). CONCLUSIONS: Our data showed that the demand for clarification regarding social rights and access to treatment reflect an unmet need for cancer patients and campaigns expanding the awareness of the population are warranted.

PCN132  
INFLUENCE OF PATIENT-REPORTED OUTCOMES ON MARKET ACCESS DECISIONS IN DECENTRALIZED MARKETS (BRAZIL, ITALY, SPAIN, AND THE UNITED STATES)  
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OBJECTIVES: To determine how impactful patient-reported outcome (PRO) data from clinical trial programs are on market access decision making in oncology. METHODS: A review of regulatory, health technology assessment (HTA), and third-party websites and published literature was the basis for six qualitative one-on-one interviews conducted with payer decision-makers (payors) in Brazil (1), Italy (1), Spain (1), and the United States (3) in 2014. RESULTS: Reviews conducted on HTA content and reimbursement decisions indicate that HTA bodies have varying levels of familiarity and confidence in PRO data. All six payers indicated that it is worthwhile to collect PRO data in clinical trials for oncology, particularly in phase 3 and postmarketing studies. The payer in Spain was aware of a specific example where PRO data were crucial to decision-making for oncology. However, all six payers indicated that PRO data will increase in importance over the next 5 to 10 years and could be a key differentiator for new therapies. Payers did not differentiate the importance of PRO data by cancer type. All six payers indicated that the quality of the PRO evidence is paramount to consideration of PRO data for new oncology drugs at the local level; one US payer noted there is significant opportunity to use PRO data to justify preferential product use and could be incorporated into hospital contracting. CONCLUSIONS: There are minimal requirements or guidelines specifically related to how payers decide on reimbursement. Therefore, inclusion of PRO data in payer decision-making is currently determined on a case-by-case basis. There is growing recognition that the patient’s perspective is important in market access in decentralized markets.

PCN134  
The Disconnect Between Funding Decisions of Cancer Drugs and Companion Diagnostic Tests in Cancer  
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OBJECTIVES: More and more pharmaceuticals receive indications that require the use of companion diagnostic tests to identify subgroups of patients who would benefit from the therapy. Many mutations have been identified in cancer and the choice of treatment frequently depends on the result of a specific companion diagnostic test. In Canada, the pan Canadian Oncology Drug Review (pCODR) assesses cancer drugs based on clinical evidence, cost-effectiveness and patient input, and make recommendations to Canada’s provinces in guiding their funding decisions. The objective of this study was to ascertain how pCODR assesses drugs requiring a companion diagnostic. METHODS: All pCODR recommendations as of were reviewed and those involving the use of a companion diagnostic were identified. A content analysis was performed to determine how companion diagnostic tests accompanying cancer drugs were reviewed by pCODR. RESULTS: pCODR has received 52 submissions since its inception and 39 recommendations have been issued. Of these recommendations, 9 involved the use of a companion diagnostic test. Both positive and negative comments around companion diagnostic tests were found among the pCODR recommendations. (Results will be tabulated). CONCLUSIONS: pCODR recommendations are dedicated to cancer drugs. However for those drugs requiring a companion diagnostic, pCODR also looks at the information related to these tests, e.g. costs and utility. However, there is no submission process for companion diagnostic tests at pCODR. Consequently, there is opportunity for inconsistency among the pCODR recommendations for cancer drugs and associated companion diagnostic tests.

PCN135  
Biomarkers: a big market access bonus? US and EU payer perspectives and prescribing patterns for Key Targeted Non-Small-Cell Lung Cancer Agents  
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OBJECTIVES: Biomarker-driven prescribing is potentially highly cost-effective as it directs premium-priced treatments towards most-likely responders. As competition intensifies between new and existing targeted treatments in oncology, how payers detect biomarkers, evaluate their value on diagnostic pharmaceuticals and how pCODR assesses drugs and associated companion diagnostic tests were reviewed by pCODR. RESULTS: pCODR has received 52 submissions since its inception and 39 recommendations have been issued. Of these recommendations, 9 involved the use of a companion diagnostic test. Both positive and negative comments around companion diagnostic tests were found among the pCODR recommendations. (Results will be tabulated). CONCLUSIONS: pCODR recommendations are dedicated to cancer drugs. However for those drugs requiring a companion diagnostic, pCODR also looks at the information related to these tests, e.g. costs and utility. However, there is no submission process for companion diagnostic tests at pCODR. Consequently, there is opportunity for inconsistency among the pCODR recommendations for cancer drugs and associated companion diagnostic tests.
cost and/or insufficient clinical advantage over other therapies. Interviewed EUs payers noted good clinical outcomes with existing agents for favorable health technology assessment (HTA) of personalized therapies; and increasingly seek cost-sharing schemes. However, most surveyed US and EU oncologists preferentially prescribe biomarker-driven agents where appropriate (e.g. 80% vs. 20% of respondents most frequently use in patients with BRAF mutation (87% vs. 70%, p<0.01)), tend to be less than 50 years of age (46% vs. 16%, p<0.01). Results were not reported. Patients who were tested for BRAF mutation. BRAF testing appears to be more prevalent in academic centers than in community hospitals.

**PCN137**

**META-ClinICANt MElANoPATIE mARRAtCHRActERIsICs AS A DETerMINING FACTOR fOR BRAF gENETIC MUTAtION TESTING AND tREATMENT IN CAnADA — A RETROSPECTIVE COHORT STUDY

Dobský D, Laporte EJ

**OBJECTIVES:** To characterize patients and treatment approaches relative to BRAF gene mutation testing. **METHODS:** An analysis of patient characteristics, diagnostic and treatment patterns including BRAF testing, age, sex, comorbidities, number of tumor sites, hospital vocation and type of therapy used was conducted using the information included in the IMS Brogan Enhanced Tumor Study database from October 2013 to September 2014. **RESULTS:** Out of 343 patients identified for BRAF mutation testing, 57% (196 pts) were BRAF positive, 36% (87 pts) BRAF negative and for 7% (16 pts) results were not reported. Patients who were tested for BRAF tended to be less than 50 years of age (46% vs. 16%, p<0.01), have none or only 1 co-morbidity (86% vs. p<0.01), have only 1 metastasis (55% vs. 45%, p<0.05), and treated in an academic facility (74% vs. 50%, p<0.01) compared to those who were not tested. BRAF negative patients were more often treated with ipilimumab compared to those who were not tested (42% vs. 10%, p<0.01). **CONCLUSIONS:** Patients characteristics emerged as an important factor for determining diagnostic and treatment protocols for metastatic melanoma patients in Canada. Younger patients and those with more severe disease characteristics are more likely to be tested for BRAF mutations and treated with ipilimumab in those without BRAF mutation. BRAF testing appears to be more prevalent in academic centers than in community hospitals.

**PCN138**

**BUREN OF SYStEMIC LIGHT-CHAIN (AL) AMYLOIDOSIS: A SYSTEMATIC LITERATURE REVIEW


**OBJECTIVES:** To conduct a systematic literature review on relapsed or refractory AL amyloidosis, focusing on clinical outcomes, epidemiology, health-related quality-of-life (HRQoL) and cost aspects. **METHODS:** MEDLINE and EMBASE databases were searched for English-language articles published in the last 10 years using search terms including “Primary/Systemic amyloidosis”, “epidemiology/prevalence/ incidence”, “therapeutics/drug therapy/outcome”, “patient-reported/quality-of-life/satisfaction/HRQoL/quality/cost” etc. Searches were manually reviewed, and relevant studies were selected for inclusion as appropriate. Additional references were obtained from recent conferences and the reference lists of selected articles. **RESULTS:** 1,414 articles were initially reviewed, and 58 included in the current review. Given the rare nature of the disease, it was difficult to obtain accurate incidence and prevalence data, but incidence estimates were found to be 2-6 cases/million/year in US. AL amyloidosis is associated with early mortality (median survival <3 years in many series) and a 42-64% rate of non-response or progression. Costly complications of AMI amyloidosis include disease-related organ failure. For example, kidney involvement is present in about 70% of patients, and rates of dialysis in patients with AL amyloidosis range from 5-18% with mean total 12-month healthcare costs (inpatient, outpatient and indirect costs) for patients receiving dialysis being $99,776. There are no disease specific patient-reported outcome (PRO) tools developed for AL amyloidosis, but patients report physical, psychological distress, anxiety and also experience unintentional weight loss. There are no consistent clinical guidelines for treatment of AL amyloidosis especially after relapse as no drug has received FDA or EMA approval for this indication. Overall, limited research efforts and significant financial and/or access challenge are major concerns with current therapies.

**CONCLUSIONS:** Limited epidemiological and health outcomes data exist in the literature for relapsed or refractory AL amyloidosis. Treatment options are insufficient. New therapies which lead to better clinical outcomes with less toxicity are needed to improve patient care.

**PCN139**

**THE IMPACT OF ENDOSCOPIC LINEAR STAPLING DEVICE STABILITY IN THORACIC SURGERY: A DELPHI PANEL APPROACH

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**OBJECTIVES:** To develop consensus statements outlining the impact of endoscopic linear stapling device stability on potential complications of thoracic surgery and the widespread use of thoracic surgeons. **METHODS:** An 8-member expert panel of practicing thoracic surgeons representing eight different countries participated in a Delphi panel process that included two anonymous surveys. The first survey included demographic, multiple-response and Likert scale type questions, which were then converted into affirmative statements for the second survey if an adequate number of respondents answered similarly. Consensus was defined a priori when ≥70% of respondents answered similarly. All 8 panels (100%) completed surveys 1 and 2. Panelists unanimously agreed an endoscopic linear stapling device with improved stability would result in less stress/ concern for critical firings, surgeries where a fellow is being trained, and robot-assisted surveillance significantly different as did the co-diagnoses of aphasia and headache (p<0.001). However, in this same period, corticosteroid and pain medication use significantly decreased as did the co-diagnoses of depression, fatigue, seizure/epilepsy, and hearing loss in the post-index period (p<0.001). In the first post-index period, multiple patients were assessed for pre- and post-index periods. Statistical comparisons between pre- and post-index were performed using McNemar’s test. **RESULTS:** A total of 1,126 patients met the inclusion criteria, with 555 patients aged ≥17 years of age (50-62%). These results indicate an increase in the use of concomitant medications (antianxiety, antidepressants, and antieptic) as well as co-diagnoses (depression, fatigue, seizure/epilepsy, and hearing loss) in the post-index period (p<0.001). However, in this same period, corticosteroid and pain medication use significantly decreased as did the co-diagnoses of aphasia and headache (p<0.001). TMZ mean starting dose, duration, and number of maintenance phase cycles was 154.4 mg (SD=77.9), 46 days (SD=12), and 7 cycles (SD=3), respectively. Following the first dose, 73% of patients experienced a TMZ dose reduction among patients with glioblastoma.

To characterize patients and treatment approaches relative to BRAF mutation. BRAF testing appears to be more prevalent in academic centers than in community hospitals.