diarrhea, dyspnea, fatigue, insomnia, nausea, neuropathy, pain, and vomiting. The final recommendations provide guidance on selection of PRO measures, implementation methods and data analysis/reporting considerations. **CONCLUSIONS:** The patient perspective is an essential component of CER. Standardizing PRO data collection in oncology trials will lead to greater comparability and improved patient-centered decision-making.

PCN107
EXAMINING KNOWLEDGE AND INFORMATION SEEKING BEHAVIORS TOWARDS BLOOD TRANSFUSION AMONG INDIVIDUALS WITH CANCER

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OBJECTIVES: Examine knowledge and information seeking behaviors towards blood transfusions among individuals with metastatic or recurrent cancer. **METHODS:** An online survey was conducted from a nationally representative patient panel in 1Q2011. All respondents were ≥18 years and diagnosed with Cancer by a physician. Participants were asked about their blood transfusion history, information seeking behaviors, and knowledge about blood transfusion. **RESULTS:** A total of 206 individuals responded to survey. 65% (n=133) were female and 25% (n=52) were over 55 years; 55% (n=114) were anemic and 45% (92) not anemic. 62% (n=128) had received blood transfusion, whereas, 38% (n=78) had no transfusions. Top two sources of information are doctor (85%) and Internet (78%). Among those previously transfused, 74% received right amount of information, whereas, 11% received too little information, and 15% received too much information. More than 90% of transfused indicated they knew the reasons for and benefits of getting a blood transfusion. Less than two-thirds received information about the costs. Over 65% of not transfused said that it is extremely important to know risks of infections, right blood type and screening techniques. Among previously transfused, about 70% agreed that they made an informed choice about receiving blood transfusions. Among the previously transfused, 78% agree that they knew the benefits compared with 68% not transfused. About 68% of transfused and not transfused agree they knew the risks of blood transfusion. **CONCLUSIONS:** Doctor's office and internet are primary sources of information about blood transfusions. Gaps in knowledge exist about benefits, risks, and costs of blood transfusions. A significant number feel that they need more information about blood transfusion to make an informed choice. Providers should consider adopting shared-decision making with their patients.

PCN108
REVIEW OF THE CONTENT VALIDITY OF THE PATIENT REPORTED OUTCOME MEASURES USED IN PATIENTS WITH BRAIN METASTASES

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OBJECTIVES: According to the FDA Patient-reported outcome (PRO) Guidance, evidence of input from the appropriate population during the development of a PRO measure is critical to determine whether a measure is applicable. A literature review was conducted to identify the symptoms and impacts (concepts) of brain metastases (BM) and the key PRO measures used in BM to compare their development and content validity. **METHODS:** Literature searches were conducted using MEDLINE®. PRO measures were reviewed for patient input and the concepts reported in the clinical literature on patients with BM were compared to those included in the identified PRO measures. **RESULTS:** A total of 34 concepts and seven key PRO measures used in BM (Functional Assessment of Cancer Therapy- General [FACT-G], FACT-Brain Tumor [FACT-Br], FACT-Brain Symptom Index [FBrSI], European Organization for Research and Treatment of Cancer-Quality of Life Questionnaire [EORTC-QLQ-C30], EORTC-Brain cancer module [EORTC QLQ-BN20], the EORTC- palliative care cancer module [EORTC QLQ-C15-PAL] and the M.D. Anderson Symptom Inventory-Brain Tumor Module [MDASI-BT]) were reviewed. The major limitation of all measures reviewed is that the items of these measures were not developed based on qualitative interviews with BM patients. In addition, these measures include concepts that were not related to BM per se as identified in the literature (e.g. itchy skin); some concepts found in the literature were not included in these instruments (e.g. dizziness). **CONCLUSIONS:** Review of the seven PRO measures used in patients with BM found that none of the measures have documented patient input in their development. The gaps between concepts reported in the literature and the PRO measures suggest the need for direct patient input in development of such measures in order to be comprehensive and yet specific to the target population.

PCN109
PROGRESSIVE WORSENING OF PATIENT-REPORTED OUTCOMES IN UNTREATED PATIENTS WITH MYELOFIBROSIS

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OBJECTIVES: COMFORT-I is a Phase III randomized, double-blind, placebo-controlled study of ruxolitinib in patients with myelofibrosis. The placebo arm provides a controlled setting to assess changes in symptomatic burden and other patient-reported outcomes (PROs) among patients not receiving myelofibrosis therapy. **METHODS:** A total of 154 patients with intermediate-2 or high-risk myelofibrosis were randomized to placebo after a 28-day washout of previous myelofibrosis therapies. Using a Total Symptom Score (TSS), myelofibrosis symptoms (night sweats, itching, abdominal discomfort, pain under ribs on left side, early satiety, and bone/muscle pain) were measured using the modified Myelofibrosis Symptom Assessment Form v2.0. Other PRO measures included the EORTC QLQ-

C30 (100-point scale), PROMIS Fatigue Scale (100-point scale), and Patient Global Impression of Change (PGIC; 7-point scale: 1=very much improved, 7=very much worse, 4=no change). Patients who withdrew or crossed over to active treatment before a study visit were not included in analyses for that visit or subsequent visits. **RESULTS:** The study included 35% intermediate-2 and 65% high-risk patients (median 2.5 years since diagnosis). By week 24, mean TSS worsened by 42% from baseline. EORTC QLQ-C30 Global Health Status and functional subscale scores also worsened from baseline to week 24, with the greatest changes in Role Functioning (mean change = -11.1) and Social Functioning (-9.0); mean PROMIS Fatigue score worsened by 9.1%. Mean PGIC score was 4.2 at week 24; 40.2% of patients perceived their condition to be worse and 29.9% unchanged. As measured by MRI/CT, spleen volume (closely related to some myelofibrosis symptoms) increased by a mean of 8.1% at week 24. **CONCLUSIONS:** In concert with increased spleen volume, patients reported worsening of myelofibrosis symptoms and other PROs over a 6-month time frame in this placebo population. Recognition of the debilitating symptoms of myelofibrosis and its progressive nature suggest early intervention with effective therapy should be considered.

PCN110
HEALTH-RELATED QUALITY OF LIFE IN ADVANCED NON-SMALL CELL LUNG CANCER (NSCLC) PATIENTS

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OBJECTIVES: Although NSCLC is associated with substantial symptom burden and significantly impacts patients' health-related quality of life (HRQoL), published data from routine care are scarce. Improving the understanding of the HRQoL impact of NSCLC will allow to comprehend more in-depth the benefit of treatments, palliative care and differing HRQOL accross health states. **METHODS:** A total 315 patients were enrolled in Australia, Belgium, Canada, France, Italy, Sweden, Turkey, the Netherlands and the UK to complete the EQ-5D and EQ-VAS questionnaires after receiving current treatment for 6-8 weeks. In order not to influence patients' perceived health, patients completed the questionnaire prior to receiving information on their tumor status. Patient demographic, disease history, treatment and adverse event data was identified from the patient chart. Utilities were calculated by applying the UK tariffs. Patients were stratified into 12 health states based on treatment line and treatment response status. Patients included had advanced stage (IIIb or IV) disease, were ≥18 years, received 1-4 lines of treatment having an ECOG performance status of 0-2 (scale: 0-4 with 4 being bedridden). **RESULTS:** Mean age at advanced NSCLC diagnosis was 64.5 years [SD=9.97] with 61.8% of patients being male, and 80.3% with stage IV disease. Fifty-two percent, 27%, and 19% of patients were on 1st, 2nd, or 3rd/4th line, respectively. Patients with progressive disease increased with treatment line; 15% (1st line), 27% (2nd line) and 46% (3rd/4th line). Mean utility in the overall sample was 0.65 [SD=0.31]. Mean utility for progression free patients on 1st, 2nd, and 3rd/4th line treatment was 0.71 [SD=0.24], 0.72 [SD=0.26], and 0.62 [SD=0.46], respectively. Mean utility for patients who progressed after 1st, 2nd and 3rd/4th line treatment was 0.68 [SD=0.21], 0.59 [SD=0.34] and 0.46 [SD=0.38], respectively. **CONCLUSIONS:** Both line of treatment and progressive NSCLC disease were found to impact patients' HRQoL assessed using EQ-5D derived utilities.

PCN111
EVALUATING MEANINGFUL CHANGE ON THE LUNG CANCER SYMPTOM SCALE IN SMALL CELL LUNG CANCER: RESULTS FROM A PHASE III CLINICAL TRIAL

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OBJECTIVES: Meaningful improvement in symptoms and quality of life (QOL) are important in treating patients with small cell lung cancer (SCLC). This analysis assessed and evaluated minimally important differences (MIDs) on the Lung Cancer Symptom Scale (LCSS) for patients with amrubicin- or topotecan-treated SCLC. **METHODS:** A prospective, multicenter, open-label, phase III randomized design study of 637 patients compared efficacy and safety of amrubicin to topotecan in treatment of SCLC. LCSS data were collected at baseline, day 1 of each cycle, and study end. The LCSS contains six symptoms (appetite, cough, dyspnea, fatigue, hemoptysis, pain), and three items (symptom distress, interference with activity level, global QOL). To assess clinically meaningful change on LCSS symptoms, MIDs were calculated as standard deviation change from baseline for each symptom item; for Symptom Burden Index (SBI) and Total Score, 1 standard error of measurement change from baseline was utilized to adjust for reliability in the SCLC population. **RESULTS:** 532 subjects with baseline and post-baseline LCSS data were analyzed (mean age=60.1; male 58.2%). Clinically relevant minimally important symptom and QOL worsening were similar to studies in non-small cell lung cancer (NSCLC). Minimal values for detecting clinically meaningful differences were: for individual symptoms, 13.7–14.5, excluding hemoptysis (4.3); for SBI, 8.7; for Total Score, 7.2. Patients on amrubicin experienced less deterioration in individual symptoms, less overall symptom burden, and improved QOL. The proportions of patients with clinically relevant deterioration in coughing favored amrubicin at Cycles 2, 6, and study end (p=0.0265, p=0.0026, p=0.0194, respectively); at Cycles 2 and 6, but not study end, deterioration in dyspnea favored amrubicin (p<0.001, p=0.0419, respectively). Similar trends favoring amrubicin were seen in the remaining symptoms. **CONCLUSIONS:** Meaningful change on the LCSS, previously