observational study. It was conducted from September 2011 to December 2012 and included a total of 1,109 patients who were recruited from four spinous centers (both orthopaedic surgery and neurosurgeons). Patients were diagnosed of having NP if the Leeds Assessment of Neuropathic Symptoms and Signs (LANSIS) pain scale criteria were ≥ 12 points. The patients were investigated to assess the treatment using pain scale (NP) and quality of life using EuroQol (EQ)-5D at baseline, after 1 week and 3 months of the surgery. RESULTS: Among 1,109 patients, at baseline, NP was identified in 404 (36%) patients and moderate/severe (74%) patients were suffering from pain in 8.6% and 4.0% patients respectively. Among the 705 patients without NP preoperatively, the prevalence of de novo NP occurred in the 1 week and 3 months of post-surgery was 3.1% and 2.3% respectively. At baseline, NP patients showed lower QoL compared with those patients (0.49 vs 0.53 p<0.001). However, NP patients improved more than their QoL compared to non-NP patients after 3 months (0.86 vs 0.84 p<0.02). Among the de novo NP patients at 3 months after surgery (n=16), the pain severity was not improved compared to the EMAs of the baseline for pain and ODI, indicating the de novo patients were suffered from severe pain and lower QoL than non-NP patients. De novo NP caused severe pain which may not easily be handled. Those study findings highlight that timely diagnosis and management of NP are required in patients with lumbar spine surgery.

**PSY84**

**The Pain Assessment for Lower Back Symptoms (PAL-S): refinement of a new PRO instrument through a mixed methods approach**

McCarry KP1, Bushnell DM2, Ramasamy A1, Liedgens H2, Blum St1, Cano S1, Martin ML2, Patrick DL2


OBJECTIVES: The Pain Assessment for Lower Back Symptoms (PAL-S) is a Patient Reported Outcome (PRO) instrument being developed to assess the key symptoms of chronic low back pain (cLBP). Qualitative development included both concept elicitation and cognitive interviews. As part of this mixed method instrument, we further evaluated and refined the PAL-S using a mixed methods approach. METHODS: Adults self-reporting a clinical diagnosis of cLBP were recruited from an existing US-based commercial survey panel to participate in a pilot qualitative study. Qualifying participants completed a web-based survey consisting of the 14-item PAL-S and items assessing clinical, treatment, and demographic characteristics. Study data was analyzed to assess item- and scale-level performance of the PAL-S using Rasch Measurement Theory analyses. Following analysis and modification, two waves of cognitive interviews were conducted to evaluate respondent understanding of the revised PAL-S. RESULTS: The dataset included 598 respondents (mean age: 55±12.6, 67.9% female, 88.0% white, and 54.0% married) who had cLBP for mean of 15.2±11.5 years. The Rasch analyses item threshold maps showed only two items having ordered thresholds, suggesting that the revised instrument was evaluated and confirmed during eight individual cognitive interviews. CONCLUSIONS: The mixed-methods approach provides valuable support in the development of a fit-for-purpose instrument assessing impacts of cLBP. Upon testing this revised PAL-1 in a second pilot quantitative study, the final measure will undergo formal validation including sensitivity to change.

**PSY85**

**Pro Claims in Orphan Medicines Approved by the European Medicines Agency (EMA) for the Treatment of Lymphoproliferative Disorders**

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OBJECTIVES: (1) To identify orphan medicines indicated for lymphoproliferative disorder approved by the European Medicines Agency (EMA); (2) To identify medicines for which a PRO evaluation was performed; (3) To list those with a PRO labeling claim, and (4) To identify reasons for not granting a PRO claim. METHODS: The search was performed in the EMA database (01/2014). The PRO claims were evaluated by type (i.e., orphan medicines). Products refused and withdrawn were excluded. The PROLabels database was searched for each product retrieved to identify any PRO claim in the label. Summary of Product characteristics (SmPCs) and CHMP Assessment Reports were retrieved for each product and analyzed to find out PRO evaluation reported in the AR and not reported in the label. RESULTS: Thirteen orphan medicines indicated in lymphoproliferative disorders were identified, representing three main indications: lymphomas (Hodgkin, systemic anaplastic large cell, T-cell lymphoblastic, mantle-cell), leukemias (chronic lymphocytic, hairy cell, acute lymphoblastic) and multiple myeloma. Only one product had a PRO claim: ofatumumab (resolution of constitutional symptoms). The label of another product (bendamustine redudetin) indicated a “resolution of 8 signs of disease”. However, there was no mention in the AR on how the symptoms were collected (patient or clinician). For one product (pomalidomide), a HQCL evaluation was mentioned in the AR, but not reported in the label. However, there was no information about this evaluation in the AR and the label is read to understand the HQQL results and the reasons for not including them in the label. CONCLUSIONS: The percentage of PRO claims in orphan medicines (77%) is inferior to the percentage of PRO claims in all EMA products (26%). This is remarkably low considering the profound effect of lymphoproliferative disorders on patients’ life. Efforts should be made to improve the reporting of PRO data in the CHMP Assessment Reports.

**PSY86**

**Psychometric validation of the newly developed phenylketonuria quality of life (PKU-QOL) questionnaires assessing the impact of phenylketonuria and its treatment on patients’ quality of life**

Bosch AM1, Burina A2, Cunningham A3, Bettiol ED4, Moreau-Stucker F5, Benmedjahed K6, Rustomali A5

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OBJECTIVES: Phenylketonuria (PKU) is a rare genetic disorder impacting phenylalanine (Phe) metabolism. Treatment involves a lifelong Phe restricted diet that is strict and socially demanding. Even when treated early and well, mild cognitive abnormalities have been associated with PKU in adults, and severe abnormalities have been seen in individuals from eight cognitive interviews confirmed patient comprehension and relevance of the revised instrument. CONCLUSIONS: The mixed-methods approach proved valuable in the development of the PAL-S and identified a need for refinement of the response scale. The measurement properties of the revised PAL-S will be evaluated in additional web-based and clinic-based quantitativa studies.

**PSY83**

**Impacts of Lower Back Pain: Refinement of the Pain Assessment for Lower Back Impacts Questionnaire (PAL-1): Using a Mixed Methods Approach**

Bushnell DM1, McCarriy KP2, Ramasamy A3, Liedgens H4, Blum St1, Cano S1, Martin ML2, Patrick DL2


OBJECTIVES: The Pain Assessment for Lower Back Impacts (PAL-1) is a patient-reported outcome (PRO) instrument being developed to assess key impacts, e.g., walking, sitting, standing, etc. associated with chronic low back pain (cLBP). Following a mixed methods approach, the PAL-1 development included qualitative work (both concept elicitation and cognitive interviews) and now a quantitative “pilot study” evaluation for further content validity. METHODS: Adults self-reporting a clinical diagnosis of cLBP were recruited from a US-based commercial survey panel. Qualifying participants completed a web-based survey consisting of the 13-item PAL-1 and items assessing clinical, treatment, and demographic characteristics. Study data was analyzed to assess item- and scale-level performance of the PAL-1 using Rasch Measurement Theory analyses. Following analysis and modification, cognitive interviews were conducted to evaluate patient understanding of the revised PAL-1. RESULTS: The 598 subjects in the pilot study reported having cLBP (mean age: 55±12.6, 67.9% female, 88.0% white, and 54.0% married). The Rasch item threshold map showed only 2 items having an ordered threshold identifying problems with the response categories. Category probability curves indicated subjects had “difficulty” endorsing items specifically in relation to the extreme options. Based on these findings, four items were removed and the response options were modified for the remaining items (from 6-point scale to 4-point). Not at all limited, Limited a little, Limited a lot, Did not do). Comprehension of the revised instrument was evaluated and confirmed

**PSY95**

**Psychometric validation of the newly developed phenylketonuria quality of life (PKU-QOL) questionnaires assessing the impact of phenylketonuria and its treatment on patients' quality of life**

Bosch AM1, Burina A2, Cunningham A3, Bettiol ED4, Moreau-Stucker F5, Benmedjahed K6, Rustomali A5

1University Medical Center of Amsterdam, Amsterdam, The Netherlands, 2University Hospital of Padova, Padova, Italy, 3Tulane University School of Medicine, New Orleans, LA, USA, 4University of Geneva Hospitals and Faculty of Medicine, Geneva, Switzerland, 5EMD Serono Inc, Billerica, MA, USA, 6Mapi, Lyon, France

OBJECTIVES: Phenylketonuria (PKU) is a rare genetic disorder impacting phenylalanine (Phe) metabolism. Treatment involves a lifelong Phe restricted diet that is strict and socially demanding. Even when treated early and well, mild cognitive abnormalities have been associated with PKU in adults, and severe abnormalities have been seen in individuals from eight cognitive interviews confirmed patient comprehension and relevance of the revised instrument. CONCLUSIONS: The mixed-methods approach proved valuable in the development of the PAL-S and identified a need for refinement of the response scale. The measurement properties of the revised PAL-S will be evaluated in additional web-based and clinic-based quantitativa studies.

**PSY86**

**Evaluating relationship between white blood cells and platelets during recovery phase in dengue hemorrhagic fever cases in punjab, pakistan**

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OBJECTIVES: Dengue infection is a major cause of disease in tropical areas with an estimated 50 million infections occurring each year and more than 2.5 billion people being at risk of infections. The main objective of this study was to investigate relationship between white blood cells and platelets during dengue hemorrhagic fever. METHODS: A retrospective multi-center study was conducted on 1000 seropositive cases of dengue fever. RESULTS: More prevalence has been observed in male (80%) as compared to female (20%). A rapid fall in white blood cells count (WBC) was observed in initial CBC reports at start of disease then
in platelet count. During recovery phase WBC count increased first by platelets count after 3-4 days. Among 1000 confirmed cases of Dengue fever 812 were considered dengue hemorrhagic fever cases on the basis of clinical finding. In most of these cases (n = 778; 96.47%), directly proportional relation was observed between WBC and platelets count. Conclusions: It was wrongly perceived in common opinion that Dengue hemorrhagic infection is still a major threat in this country. In normal even the white blood cells counts is getting better during recovery phase.

White blood cells production during recovery phase is a good indicator about recovery of disease rather than focused on platelets counts production.

**PSY78**

**PHYSICIANS’ AND PATIENTS’ PREFERENCES OVER THE ATTRIBUTES OF BIOLOGICAL AGENTS USED IN THE TREATMENT OF RHEUMATIC DISEASES IN SPAIN: A CONJOINT ANALYSIS**

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**OBJECTIVES:** To define the importance values assigned to the attributes of biological agents used to treat rheumatoid patients and patients with rheumatic diseases: rheumatoid arthritis (RA), anklyosing spondylitis (AS) and psoriatic arthritis (PA).

**METHODS:** Observational, cross-sectional design based on conjoint analysis. RA and PA patients diagnosed at least 2 years prior and currently or previously (≤ 1 year ago) receiving RA for a minimum of 1 year were consecutively recruited. Rheumatologists with at least 3 years experience on RA were involved. A total of 488 patients [male 50.6%; mean (SD) age 46.4 (9.1) years; RA 33.8%, AS 32.4%, PA 33.8%; mean time of diagnosis=12.6 (8.2) years] and 136 rheumatologists [male=50.4%, mean age 46.4 (9.1) years; mean time of practice=11.6 (7.6) years]. Both sets of attributes selected by patients and rheumatologists, respectively, were: ‘Pain relief and improvement of the functional capacity’ (RI=49.1% and 48.9%), ‘Risk of adverse events’ (RI=31.8% and 31.5%), ‘Administration method’ (RI=10.2% and 11.4%) and ‘Time to perceive the need for a new dose’ (RI=12.4%). The ideal joint treatment is only achieved by patients and physicians, respectively. Conclusions: Although efficacy and safety are key for patients with rheumatic diseases and rheumatologists to make a choice over RA, the need for a low frequency of administration and the administration method also play an important role as preference attributes for RA in Spain.

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**PSY90**

**A SYSTEMATIC LITERATURE REVIEW OF THE HUMANISTIC BURDEN OF MYELOMA: Rizzo M1, Xu Y2, Panjabi S3, Desrichio S1

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**OBJECTIVES:** We conducted a systematic literature review to identify published evidence from observational studies on the humanistic burden of multiple myeloma (MM).**METHODS:** We searched MEDLINE, Embase, EconLit, and the Cochrane Library for English-language articles and analyzed them qualitatively.**RESULTS:** The review identified 20 publications based on 18 observational studies, these were mainly cross-sectional in design (n=14). Most studies (n=15) examined populations with MM in general, typically without stating the proportion with relapsed (R) or relapsed and refractory (RR) MM. Fewer studies examined relapsed (R) or relapsed and refractory (RR) MM (n=2) or RMM/RRM (n=3). Health-related quality of life (HRQoL) was typically assessed using validated cancer-specific instruments (e.g., the EORTC-QLQ-C30; n=9); and the MM-specific EORTC-QLQ-MM20 (n=4). On average, patients with MM had poorer HRQoL compared to the general population (n=6), and compared to patients with certain other hematologic cancers (n=2). MM patients whose disease was diagnosed from diagnosis to 11 years had greater physical functional impairment (p < 0.001) than other hematologic cancer patients. Other complaints included fatigue, bone pain, tingling, and non-specific pain. Patients on active treatment had worse side effects than those in a first treatment-free interval (p < 0.001), the latter had no financial burden. There is an advantage of MM patients over RA regarding role, physical function, future perspectives, and body image (all p < 0.05). Between baseline and one year, patients experienced worsening on the EORTC-QLQ-C30 global health scale (p < 0.001) and in role, physical, emotional, and pain scores (all p < 0.05). Symptomatic patients had lower functional scores (p < 0.05) than asympomatic patients; those with severe symptoms had lower EORTC-QLQ-C30 global health scores (p < 0.05; moderate/severe: p ≤ 0.05). Fatigue, bone pain, and anemia were associated with worse disease-specific QoL (p < 0.001). Conclusions: Patients with severe symptoms had lower EORTC-QLQ-C30 global health scores (p < 0.05; moderate/severe: p ≤ 0.05). Fatigue, bone pain, and anemia were associated with worse disease-specific QoL (p < 0.001).