observational study. It was conducted from September 2011 to December 2012 and included a total of 1,109 patients who were scheduled for lumbar spinal surgery from 44 spinal centers (both orthopaedic surgery and neurosurgeons). Patients were diagnosed of having NP if the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) pain scale criteria were ≥12 points. The patients were investigated to assess their pain severity using pain numeric rating scale (NRS) and quality of life using EuroQol (EQ)-5D at baseline, after 1 week and 3 months of the surgery. **RESULTS:** Among 1,109 patents, at baseline, NP was identified in 404 (36%) patients. After 1 week and 3 months of the surgery, NP was found 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 non-NP patients (0.49 vs 0.53 p<.001). However, NP patients improved more their QoL compared to non-NP patients after 3 months (0.86 vs 0.84 p=.029). Among the de novo NP patients at 3 months after surgery (n=16), the pain severity was not improved after 1 week and 3 months of the surgery. **CONCLUSIONS:** In Korea, NP 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.

PSY82

THE PAIN ASSESSMENT FOR LOWER BACK SYMPTOMS (PAL-S): REFINEMENT OF A NEW PRO INSTRUMENT THROUGH A MIXED METHODS APPROACH

McCarrier KP[1], Bushnell DM[1], Ramasamy A[2], Liedgens H[3], Blum SI[4], Cano S[5], Martin ML[1], Patrick DL[6]

[1]*Health Research Associates, Inc., Seattle, WA, USA,* [2]*Forest Research Institute, Jersey City, NJ, USA,* [3]*Grünenthal GmbH, Aachen, Germany,* [4]*GlaxoSmithKline, Collegeville, PA, USA,* [5]*ScaleReport, Stotfold, UK,* [6]*University of Washington, Seattle, WA, USA*

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 the ongoing development of the 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 quantitative 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: 55.5±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 respondents experienced increased difficulty distinguishing between options at the lower levels of the 0-10 scale. Simulations collapsing the responses to a best-fit 4-point response scale resulted in improved ordering of thresholds, suggesting a more optimal response option structure. Based on these findings, the numeric response scale of the PAL-S items was replaced with a 4-point verbal rating scale incorporating response choices such as *not at all*, *slight*, *moderate*, and *severe*. Findings from eight cognitive interviews confirmed patient comprehension and relevance of the revised instrument. **CONCLUSIONS:** The mixed-methods approach proved valuable to the ongoing development of the PAL-S, as Rasch analyses 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 quantitative studies.

PSY83

IMPACTS OF LOWER BACK PAIN: REFINEMENT OF THE PAIN ASSESSMENT FOR LOWER BACK-IMPACTS QUESTIONNAIRE (PAL-I) USING A MIXED METHODS APPROACH

Bushnell DM[1], McCarrier KP[1], Ramasamy A[2], Liedgens H[3], Blum SI[4], Cano S[5], Martin ML[1], Patrick DL[6]

[1]*Health Research Associates, Inc., Seattle, WA, USA,* [2]*Forest Research Institute, Jersey City, NJ, USA,* [3]*Grünenthal GmbH, Aachen, Germany,* [4]*GlaxoSmithKline, Collegeville, PA, USA,* [5]*ScaleReport, Stotfold, UK,* [6]*University of Washington, Seattle, WA, USA*

OBJECTIVES: The Pain Assessment for Lower Back-Impacts (PAL-I) 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-I 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-I and items assessing clinical, treatment, and demographic characteristics. Study data was analyzed to assess item- and scale-level performance of the PAL-I using Rasch Measurement Theory analyses. Following analysis and modification, cognitive interviews were conducted to evaluate patient understanding of the revised PAL-I. **RESULTS:** The 598 subjects in the pilot study reported having cLBP (mean of 6.1 on 11-point numerical rating scale, 0=no pain). Subjects experienced cLBP for 0.3 to 66 years (mean 15.2, SD 11.5), were 55.5 years old (SD 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 4-point: *Not at all limited*, *Limited a little*, *Limited a lot*, *Did not do*). Comprehension of 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-I in a second pilot quantitative study, the final measure will undergo formal validation including sensitivity to change.

PSY84

PRO CLAIMS IN ORPHAN MEDICINES APPROVED BY THE EUROPEAN MEDICINES AGENCY (EMA) FOR THE TREATMENT OF LYMPHOPROLIFERATIVE DISORDERS

Acquadro C[1], Perret C[2], Arnould B[3]

[1]*Mapi Research Trust, Lyon, France,* [2]*MAPI Research Trust, Lyon, France,* [3]*Mapi, Lyon, France*

OBJECTIVES: 1) To identify orphan medicines indicated for lymphoproliferative disorders 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 on the EMA website (06/21/2014). The products were browsed 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 (SMPc) and CHMP Assessment Reports (AR) were retrieved for each product and analyzed to find out about 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 (brentuximab vedotin) indicated "resolution of B symptoms." However, there was no mention in the AR on how the symptoms were collected (patient or clinician). For one product (pomalidomide), a HRQL 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 reader is left to wonder about the HRQL results and the reasons for not including them in the label. **CONCLUSIONS:** The percentage of PRO claims in orphan medicines (7.7%) 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.

PSY85

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 AM[1], Burlina A[2], Cunningham A[3], Bettiol EO[4], Moreau-Stucker F[5], Benmedjahed K[6], Regnault A[6]

[1]*University Hospital of Amsterdam, Amsterdam, The Netherlands,* [2]*University Hospital of Padova, Padova, Italy,* [3]*Tulane University School of Medicine, New Orleans, LA, USA,* [4]*University of Geneva Hospitals and Faculty of Medicine, Geneva, Switzerland,* [5]*EMD Serono Inc, Billerica, MA, USA,* [6]*Mapi, 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 seen. PKU can affect quality of life in individuals and their families. The phenylketonuria–quality of life (PKU-QOL) questionnaires are the first PKU-specific QOL questionnaires ever developed. The study aimed to perform the psychometric validation of these questionnaires. **METHODS:** An observational study was conducted in France, Germany, Italy, The Netherlands, Spain, Turkey and the UK to finalize and validate PKU-QoL questionnaires in individuals with treated PKU aged 9–11, 12–17 and ≥18 years, and in parents of individuals <18 years. Questionnaires were assessed for reliability (internal consistency, test–retest), concurrent validity (using three generic questionnaires adapted to the respondent: PedsQOL, SF-36 for adults and CHQ-PF28) and clinical validity (using PKU severity and overall assessment of patient health status). **RESULTS:** In total, 559 participants (306 individuals, ages 9–45 years; 253 parents, ages 24–66 years) were included in the analysis. Return rate and quality of completion of the questionnaires were good, indicating good acceptability. Scores were defined to assess all relevant aspects of experiences: PKU symptoms, impact of PKU, dietary protein restriction and supplementation. Reliability and validity were satisfactory overall for the adolescent, adult and parent PKU-QoL questionnaires, and slightly weaker but acceptable for the child version. **CONCLUSIONS:** The four PKU-QOL questionnaires are valid and reliable instruments for assessing the specific quality of life aspects that are affected in individuals with PKU of different age groups (children, adolescents and adults) and their parents, and are available in seven languages. They are very promising tools for focused evaluation of PKU impact on individuals and parents in different countries, and for monitoring the efficacy of therapeutic strategies.

PSY86

EVALUATING RELATIONSHIP BETWEEN WHITE BLOOD CELLS AND PLATELETS DURING RECOVERY PHASE IN DENGUE HEMORRHAGIC FEVER CASES IN PUNJAB, PAKISTAN: A RETROSPECTIVE STUDY

Rasool F[1], Ahmad M[2], Masood I[2], Khan HMS[3]

[1]*University of Punjab, Lahore, Pakistan,* [2]*The Islamia University of Bahawalpur, Bahawalpur, Pakistan,* [3]*Islamia University Bahawalpur, The Islamia University of Bahawalpur, Pakistan*

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 relation between white blood cells and platelets during recovery phase in 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 880 (88%) as compared to female 120 (12%). A rapid fall in white blood cells count (WBC) was observed in initial CBC reports at start of disease then