OBJECTIVES: Adherence to iron chelation therapy (ICT) is essential for patients with transfusion-dependent anemia (TDA) (e.g., sickle cell disease [SCD] and thalassemia major). ICT aims to reduce iron overload and minimize the risk of complications related to iron accumulation. Adherence has been noted as especially problematic for children and adolescents. In order to measure compliance and treatment satisfaction in young children, the Satisfaction with Iron Chelation Treatment (SIT); instrument (initially developed for use by clinicians for children 10 years of age and younger) was modified to be an observer-reported outcome (ObsRO) measure to be administered electronically to caregivers. In addition, three other ObsROs were developed measuring compliance, palatability, and gastrointestinal (GI) symptoms related to treatment benefit of a new ICT formulation. METHODS: Subjects included 10 caregivers of children with TDA. Informed consent was obtained. Two sets of face-to-face cognitive interviews were conducted iteratively with modifications to items and further defining or modifications. Interviews began with an open-ended question to elicit caregivers’ and their reports of their child’s experiences with ICT. Interviews were audio recorded and transcribed. Data were analyzed using ATLAS.ti software. RESULTS: Three interviews conducted 10 caregiver interviews in 6 US cities. Caregivers were 90% female aged 35-65 (mean=48). Children of caregivers included those with SCD (80%) and thalassemia (20%) and were 60% female, aged 2-17 (mean=9). Responses to the open-ended question confirmed several concepts in the modified SIT and the need for new ObsROs. Interviewers included 17 items, Compliance (2 items), Palatability (4 items), and GI Symptom Diary (6 items). Changes were made to each to ensure comprehension, relevance, lack of redundancy, and appropriate response options. CONCLUSIONS: Evidence supports the content validity of the modified SIT; Compliance, Palatability, and GI Symptom Diary questionnaires. Use in clinical research awaits tests of validity, reliability, and responsiveness.

PSY77 IMPACT OF PULMONARY EXACERBATIONS ON EQ-5D MEASURES IN PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE
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OBJECTIVES: The focus of this study was to assess the impact of PEs on health-related quality of life (HRQoL) using the five dimensions of the EQ-5D-5L in a large population of patients with COPD. EQ-5D-5L scores were collected in the 8-week post- exacerbation periods were examined after pooling observations across study treatments and visits. RESULTS: A total of 146 PEs were experienced by 72 (44.7% of total 161) patients, including 52 (36.6%) PEs that required hospitalization. Mean (±SD) duration was 30.0±22.2 days for PEs requiring hospitalization (n=48) and 20.6±11.4 days for those not requiring hospitalization (n=98) (9 PEs had missing end dates). For PEs requiring hospitalization, mean (±SD) EQ-5D index/EQ-VAS score within 1-8 weeks prior to PE start were 0.91 (±0.13)/75.5 (±14.2), respectively. The lowest average EQ-5D index/EQ-VAS scores were reached within 1 week of PE start; mean scores within 1 week were 0.76±0.33 (p<0.04) vs. 1.8 weeks prior to PE) /63.7±24.1 (p<0.05). Corresponding values for PEs not requiring hospitalization were 0.89±0.16/73.4±16.1 (p<0.05). CONCLUSIONS: HRQoL was negatively affected by PEs requiring hospitalization. Reducing PEs requiring hospitalization is likely to improve health-related quality of life among these patients.

PSY78 IS OBESITY A PROBLEM IN BRAZIL?
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OBJECTIVES: This study investigated the effect of BMI on quality of life, pro- voked by iron chelation therapy (ICT). Interviews were audio recorded and transcribed. Data were analyzed using ATLAS.ti software. RESULTS: Three interviews conducted 10 caregiver interviews in 6 US cities. Caregivers were 90% female aged 35-65 (mean=48). Children of caregivers included those with SCD (80%) and thalassemia (20%) and were 60% female, aged 2-17 (mean=9). Responses to the open-ended question confirmed several concepts in the modified SIT and the need for new ObsROs. Interviewers included 17 items, Compliance (2 items), Palatability (4 items), and GI Symptom Diary (6 items). Changes were made to each to ensure comprehension, relevance, lack of redundancy, and appropriate response options. CONCLUSIONS: Evidence supports the content validity of the modified SIT; Compliance, Palatability, and GI Symptom Diary questionnaires. Use in clinical research awaits tests of validity, reliability, and responsiveness.

PSY79 THE MULTICENTRIC CASTLEMAN’S DISEASE (MCD) -SYMPTOM SCALE (MCD-SS): DEVELOPMENT AND VALIDATION OF A PATIENT-REPORTED OUTCOME (PRO) MEASURE FOR AN ULTRA-ORPHAN DISEASE
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OBJECTIVES: Adherence to iron chelation therapy (ICT) is essential for patients with transfusion-dependent anemia (TDA) (e.g., sickle cell disease [SCD] and thalassemia major) to reduce iron overload and minimize the risk of complications related to iron accumulation. Adherence has been noted as especially problematic for children and adolescents. In order to measure compliance and treatment satisfaction in young children, the Satisfaction with Iron Chelation Treatment (SIT); instrument (initially developed for use by clinicians for children 10 years of age and younger) was modified to be an observer-reported outcome (ObsRO) measure to be administered electronically to caregivers. In addition, three other ObsROs were developed measuring compliance, palatability, and gastrointestinal (GI) symptoms related to treatment benefit of a new ICT formulation. METHODS: Subjects included 10 caregivers of children with TDA. Informed consent was obtained. Two sets of face-to-face cognitive interviews were conducted iteratively with modifications to items and further defining or modifications. Interviews began with an open-ended question to elicit caregivers’ and their reports of their child’s experiences with ICT. Interviews were audio recorded and transcribed. Data were analyzed using ATLAS.ti software. RESULTS: Three interviews conducted 10 caregiver interviews in 6 US cities. Caregivers were 90% female aged 35-65 (mean=48). Children of caregivers included those with SCD (80%) and thalassemia (20%) and were 60% female, aged 2-17 (mean=9). Responses to the open-ended question confirmed several concepts in the modified SIT and the need for new ObsROs. Interviewers included 17 items, Compliance (2 items), Palatability (4 items), and GI Symptom Diary (6 items). Changes were made to each to ensure comprehension, relevance, lack of redundancy, and appropriate response options. CONCLUSIONS: Evidence supports the content validity of the modified SIT; Compliance, Palatability, and GI Symptom Diary questionnaires. Use in clinical research awaits tests of validity, reliability, and responsiveness.

PSY80 I DON’T KNOW HOW IT HAPPENED OR WHEN EVERYTHING CHANGED. IT’S LIKE I BLINKED AND ALL OF A SUDDEN, I DIDN’T RECOGNISE MY OWN BODY*: USING QUALITATIVE INSIGHTS TO DEVELOP A CONCEPTUAL MODEL TO UNDERSTAND THE LIVED EXPERIENCE OF PATIENTS WITH SYSTEMIC SCLEROSIS
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OBJECTIVES: Systemic sclerosis (SSc) is a rare, multisystem chronic disease characterized by the occurrence of one or more symptom clusters with high morbidity and a significant effect on patients’ health-related quality of life. Qualitative insights can provide rich context to the patients’ experience of SSc and help inform the development of a conceptual model. The objective of this study was to explain, with graphically or narrative form, the main things to be studied - the key concepts, factors and variables – and the presumed relationships between them. METHODS: A systematic review of SSc used for the conceptual model of SSc. RESULTS: This study was a nationwide, multi-centered, prospective, and observational study of patients with SSc in Germany. We reviewed qualitative literature (published since 2000 to limit the search) in which the experiences of living with SSc were described. We also reviewed social media blogs/forums to identify additional concepts and provide supporting quotes. Concepts were identified by independent researchers who collaboratively developed the model. RESULTS: Twelve qualitative studies and 150 social media posts were reviewed. The review identified 56 symptom concepts, which were categorised into 13 domains (peripheral, cognitive, pain, neurological, cardiorespiratory, ophthalmological, gastrointestinal, fatigue, nausea, weight, oesophageal, dizziness, nausea) and 48 impact concepts, which were categorized into 8 domains (daily living, diet, social, clothing, work, physical and psychological functioning). Of note, nausea and dizziness were identified only through the social media review. CONCLUSIONS: A conceptual model for SSc was developed based on qualitative insights. The model depicts the diverse range of symptoms and impacts experienced by patients. By incorporating a social media review, relevant symptoms, which would not have otherwise been identified, were found and included in the model. This research is an important first step in identifying the most relevant and conceptually comprehensive outcomes assessments for clinical research/practice.

PSY81 PREVALENCE OF NEUROPATHIC PAIN AND ITS DISEASE BURDEN IN KOREA PATIENTS WITH LUMBAR SPINE SURGERY
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OBJECTIVES: The objectives of this study were to investigate the prevalence of Neuropathic Pain (NP) and newly occurred (de novo) NP postoperatively. This study also aimed to identify the disease burden (pain severity and quality of life [QoL]) of NP. METHODS: This study was a nationwide, multi-centered, prospective, and...
observational study. It was conducted from September 2011 to December 2012 and included a total of 1,109 patients who were evaluated from 44 spinal centers (both orthopaedic surgery and neurosurgeons). Patients were diagnosed of having NP if the Leeds Assessment of Neuropathic Symptoms and Signs (LANSN) pain scale criteria were ≥ 12 points. The patients were investigated to assess the impact of pain using six scaling scale (NP) related to the quality of life using EuroQol (EQ)-5D at baseline, after 1 week and 3 months of the sur-

gery. RESULTS: Among 1,109 patients, at baseline, NP was identified in 404 (36%) patients and 289 patients (26%) patients were 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 (p=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=0.09). Among the de novo NP patients at 3 months after surgery (n=16), the pain severity was not improved, but a decrease on the EMAS was observed. The CONCLUSIONS: NP was mainly caused by back surgery; individuals suffering 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.

PSY83
THE PAIN ASSESSMENT FOR LOWER BACK SYMPTOMS (PAL-S): REFINEMENT OF A NEW PRO INSTRUMENT THROUGH A MIXED METHODS APPROACH
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OBJECTIVES: The Pain Assessment for Lower Back-Impacts (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 refinement 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 mixed-methods 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 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 (p=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=0.09). Among the de novo NP patients at 3 months after surgery (n=16), the pain severity was not improved, but a decrease on the EMAS was observed. The CONCLUSIONS: NP was mainly caused by back surgery; individuals suffering 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
PRO CLAIMS IN ORPHAN MEDICINES APPROVED BY THE EUROPEAN MEDICINES AGENCY (EMA): A SYSTEMATIC REVIEW OF THE IMPACT OF LYMPHOPLASMA PROCLAMATIONS ON THE LABELING OF ORPHAN MEDICINES
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OBJECTIVES: (1) to identify orphan medicines indicated for lymphoproliferative dis-

order 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 22 February 2014. RESULTS: Nineteen medicines were identified 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 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 label 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 label 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
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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 cogni-
tive impairment is still prevalent; older people experience a reduced quality of life in individual and family life. The phenylketonuria–quality of life (PKU-QOL) questionnaires are the most widely used PKU assessment tools. 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 label 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.

PSY86
EVALUATING RELATIONSHIP BETWEEN WHITE BLOOD CELLS AND PLATELETS DURING RECOVERY PHASE IN DENGUE HEMORRHAGIC FEVER CASES IN PUNJAB, PAKISTAN: A RETROSPECTIVE STUDY
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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 at risk of infections. The main objective of this study was to investigate relationships between white blood cells and platelets during the 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 during eight individual cognitive interviews. CONCLUSIONS: The mixed-methods approach provides valuable information in the development of a future PRO 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.