gain category (3.45, 3.97) and increased with increasing categorical weight loss: B 7.63, 7.61; C 10.61, 10.92; D 12.61, 16.50; E 17.27, 15.35. Changes in SF-36 physical component summary scores, but not mental component summary scores, followed a similar pattern. **CONCLUSIONS:** We observed higher proportions of subjects achieving greater categorical weight loss with liraglutide 3.0 mg versus placebo as adjunct to D&E. With greater categorical weight loss, greater improvements in IWQOL-Lite total and SF-36 physical component summary scores were observed.

PSY92
COGNITIVE TESTING OF A MODIFIED VERSION OF THE FACES PAIN SCALE-REVISED IN CHILDREN WITH SICKLE-CELL DISEASE

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OBJECTIVES: Sickle-cell disease (SCD) manifests clinically as severe pain episodes in various locations of the body. Patients with SCD also experience chronic daily pain, which profoundly affects quality of life. Cognitive interviews were conducted to evaluate comprehension and usability of a modified version of the Faces Pain Scale-Revised (Modified FPS-R), which asks children to rate their worst pain today using an electronic device. **METHODS:** In-person interviews were conducted in the US with children aged 4-17 years with SCD and their parent/legal guardian. Children who were unable to read or needed guidance were assisted by their parent/legal guardian using written administration guidelines. Children were asked questions about their pain experience, understanding of the instrument, and ability to use the electronic device. Parents/legal guardians were debriefed on the administration guidelines, assisting their child, use of the electronic device, and their child's pain experience. **RESULTS:** The sample included 22 African American children (13 females/9 males; 7=4-5 year-olds, 12=6-11 year-olds and 3=12-17 year-olds). Pain was most commonly reported to occur in the legs, back, arms, stomach, or head. Those aged ≥7 years were able to demonstrate good understanding of the Modified FPS-R item and response scale and ability to use the electronic device. Children 4-6 years were generally not familiar with "discomfort" and many did not know the meaning of "pain". It was unclear whether these children were able to consider their worst pain over the course of the day and respond accordingly. Parents/legal guardians noted that the instrument instructions were clear and that the administration guidelines provided simplified, standardized direction for young children and those unable to read without assistance. **CONCLUSIONS:** The Modified FPS-R used with the administration guidelines where parental assistance is needed, is an appropriate measure of sickle-cell pain over the course of a day for children aged ≥7 years.

PSY93
REPORTING INSTRUMENTS OF PATIENT REPORTED OUTCOMES IN ORPHAN DISEASE

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OBJECTIVES: To identify patient-reported outcomes (PROs) evaluating quality of life (QoL) in Gaucher Disease (GD) after formation of Rare-Diseases Program in 2010 by the Center for Drug Evaluation and Research under United States Food and Drug Administration with a mission to acknowledge patient's perceptions on treatment benefits. **METHODS:** Embase® and MEDLINE®databases were searched from January 2010 to May 2015. Studies published in English language were included irrespective of study designs by two independent reviewers with discrepancies reconciled by a third independent reviewer. **RESULTS:** Out of 325 studies retrieved from biomedical databases, only nine studies reporting seven different PRO instruments were included. Details of study conduct were adequately reported with no significant difference between treatment groups. Six generic instruments were identified from the included studies, Short Form Health Survey with 36-items (SF-36; 5 studies), 12-items (SF-12; 1 study), the European Quality of Life - Five Dimensions (EQ-5D; 2 studies), Functional Assessment of Chronic Illness Therapy - Fatigue (FACT-F; 1 study), Brief Pain Inventory (BPI; 1 study), and the Visual Analogue Scale (VAS; 1 study). Only one study used the disease-specific Type 1 Gaucher Disease - Disease Severity Scoring System (GD-DS3) providing a reliable method of assessing both intra- and inter-patient severity indicating an impact of pain on the QoL. Overall, the results correlated with clinical outcomes in GD patients demonstrating poorer physical functioning than healthy controls. A review of HTA submissions showed that current evidence on QoL was not sufficient to assess disease impact with the French HTA agency (HAS) particularly encouraging the need to assess QoL to support evidence on treatment effects. **CONCLUSIONS:** Variability in use of PRO instruments was seen among the included studies. Disease specific PRO measures are highly acceptable and need to be developed in orphan disease for better evaluation of QoL.

PSY94
IMPACT OF PAIN SEVERITY ON PATIENT-REPORTED OUTCOMES OF INDIVIDUALS WITH CHRONIC LOWER BACK PAIN IN JAPAN

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OBJECTIVES: To quantify the impact of pain severity on patient-reported outcomes among individuals diagnosed with chronic lower back pain (CLBP) in Japan. **METHODS:** Data came from the 2012 Japan National Health and Wellness Survey (N=29,997), a web-based survey of individuals in Japan aged ≥18 years. This analysis included respondents diagnosed with lower back pain of ≥3 months' duration. Measures included the SF-36v2, Patient Health Questionnaire (PHQ-9), Generalized Anxiety Disorder 7-item (GAD-7) scale, Work Productivity and Activity Impairment questionnaire, and self-reported all-cause healthcare visits (6 months). Generalized linear models with appropriate link functions were used to assess the relationship between outcomes and severity of pain in the prior week as reported on a visual analog scale ranging from 0 (No pain) to 10 (Pain as bad as you can imagine)

while controlling for length of diagnosis, sociodemographics, and general health characteristics. **RESULTS:** A total of 346 respondents were included in the analysis; mean age was 55 years, 55% were male, and 55% were employed. Pain severity was 3/10 for the 1st quartile, 5/10 for the median, and 7/10 for the 3rd quartile of this sample. Increasing severity was associated with lower scores for mental (MCS) and physical component summaries (PCS) and SF-6D health utility, higher depression (PHQ-9) and anxiety (GAD-7) scores, greater absenteeism and presenteeism, greater activity impairment, more healthcare provider visits, and more emergency visits (all p<0.05). As pain severity increased from the 1st to 3rdquartile, MCS, PCS, and SF-6D all declined more than the minimally important difference, while work and activity impairments approximately doubled. **CONCLUSIONS:** The impact of CLBP on HRQoL, depression and anxiety symptoms, impairment to work and daily activities, and healthcare use increases with the severity of pain. Interventions reducing severity of pain may improve numerous health outcomes even if the pain cannot be eliminated.

PSY95
THE RELATIONSHIP BETWEEN DISEASE SEVERITY AND QUALITY OF LIFE IN PATIENTS WITH MODERATE TO SEVERE PSORIASIS

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OBJECTIVES: Psoriasis is prevalent in approximately 3% of the population, and often results in significant quality of life losses. The aim of this study was to investigate the relationship between disease severity and quality of life (QOL) measured by the psoriasis area severity index (PASI) and EQ-5D, respectively. **METHODS:** Longitudinal data from a population-based registry in Sweden (PsoReg) were analysed. PsoReg includes patients with moderate to severe psoriasis receiving systemic treatment from a specialist with data available from 2006 to 2014. The analysis was conducted using all complete observations for adult patients at each healthcare contact date. A fixed effects (FE) model was estimated, where time-invariant patient-specific effects were modelled. Time-invariance refers to variables that do not change over time, such as sex or personality. PASI, PASI squared, age, body mass index, smoking status, and presence of psoriatic arthritis were included in the regression as independent variables. PASI squared accounts for a nonlinear relationship between PASI and EQ-5D. The model was tested for the appropriateness of random effects and existence of group-wise homoscedasticity, both of which were rejected at an alpha level of 0.01. Therefore the final model used FE and robust standard errors. **RESULTS:** The estimation utilised 15,099 observations in 3,838 groups, resulting in an average of 3.9 observations per patient. The results indicate that each unit increase in PASI is correlated with a reduction in EQ-5D, but at a decreasing rate: the estimates of PASI and PASI squared were -0.0178 (p<0.001) and 0.0002 (p<0.001) respectively. This implies that an increase in PASI of 10 (20) units results in a decrease in EQ-5D of 0.1571 (0.2717) holding other variables constant at their respective means. The (adjusted) R2 was (0.5279) 0.6481. **CONCLUSIONS:** QOL in psoriasis patients is decreasing as disease severity increases, but at a decreasing rate.

PSY96
EVALUATION OF PATIENTS' QUALITY OF LIFE OF PREOPERATION AND EARLY POSTOPERATION AFTER TOTAL HIP AND KNEE ARTHROPLASTY

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OBJECTIVES: Total hip and knee arthroplasty operations are commonly performed to improve patients' quality of life. The aim of this study is evaluation of patients' quality of life of preoperation and early postoperation after total hip and knee arthroplasty. **METHODS:** This study included 26 patients undergoing total hip and knee arthroplasty. After the literature review, 15-items questionnaire was prepared for collecting data related to sociodemographic, medical and functional status information, including age, sex, previous hip and knee arthroplasty and pain level. Quality of life were measured by using the EQ-5D and Visual Analog Scale (VAS). During the study, questionarries were administered to patients 2 times: one week prior to operation and 45 days following operation. **RESULTS:** The average age of participants was 67,12 years (SD: 10,527). Participants were composed of 80,8% females and 19,2% males. Small improvements were reported for pain and functional status after the operations, while large changes were seen in the patients' quality of life. The EQ-5D scores improved significantly preoperatively to postoperatively (p<0,05) (0,322 vs 0,844). Similarly, there was a significant improvement in VAS scores preoperatively to postoperatively (p<0,05) (4,72 vs 7,78). **CONCLUSIONS:** Total hip and knee arthroplasties are well accepted as reliable and suitable surgical procedures to return patients to function and improve the quality of life of patients'.

PSY97
HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH TRANSTHYRETIN FAMILIAL AMYLOID POLYNEUROPATHY

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OBJECTIVES: Transthyretin Familial Amyloid Polyneuropathy (TTR-FAP) is a rare, progressive, debilitating and life-threatening neurodegenerative disease. The purpose of this study was to assess the health-related quality of life (HRQoL) factors for TTR-FAP patients. **METHODS:** HRQoL was measured using the validated EuroQoL five dimensions three levels (EQ-5D-3L) questionnaire being the index score calculated trough the Portuguese scoring algorithm. TTR-FAP symptomatic patients specific data (n = 566) extracted from Transthyretin Amyloidosis Outcomes Survey (THAOS) registry. Demographic variables include gender and age. Clinical variables include disease onset (early/late), polyneuropathy disability (PND) score, liver transplant and pharmacologic treatment. Econometric analyses were carried out to identify factors that impact TTR-FAP HRQoL. **RESULTS:** In a scale from -0.50 to 1.00 the average utility score 0.50(0.37) for symptomatic TTR-FAP patients. Within TTR-FAP population, significant statistical effect (p-value <0.005) was