while controlling for length of diagnosis, sociodemographics, and general health characteristics.

**RESULTS:** A total of 294 patients were included, of whom 158 (53.7%) were females and 136 (46.3%) were males. The 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 (PCS) 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 DLE. With greater weight loss, greater QoL and greater improvement in HbA1c-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

**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 treatments. METHODS: To characterize in a total 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 conflicts of interest.

**RESULTS:** Out of 325 studies retrieved from January 2010 to May 2015. Studies published in English language were included. 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 FRHA agency (RAS) 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: CLBP data were obtained from the 2010 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), General Health Questionnaire (GHQ-12), Generalized Anxiety Disorder 7 items (GAD-7), Patient Health Questionnaire-5 items (PHQ-5), Impact questionnaire, and self-reported all-case healthcare visits (6 months). Generalized linear models with different link functions were used to assess the relationship between outcome measures and severity of pain for the prior week as reported on a visual analog scale ranging from 0 (No pain) to 10 (Pain as bad as you can imagine)

**Results:** We observed higher proportions of subjects achieving greater categorical weight loss with liraglutide 3.0 mg versus placebo as adjunct to DLE. With greater weight loss, greater QoL and greater improvement in HbA1c-Lite total and SF-36 physical component summary scores were observed.