OBJECTIVES: Hemophilia is a chronic disease typically diagnosed in infancy, characterised by a deficiency of a protein necessary for normal blood clotting. Taking care of a child with hemophilia (CWH) may cause burden for caregivers. We aimed to develop a first “Hemophilia associated Caregiver Burden Scale” (HEMOCABTM) assessing the burden of hemophilia for caregivers of CWH.

METHODS: Questionnaires were given to regular or episodic infusions clinic patients and caregivers. The revised HEMOCABTM consisted of 108 items grouped in 13 domains. HEMOCABTM was pilot-tested in 40 caregivers of CWH with a mean age of 39.3±8.9. The majority of CWH had hemophilia A (95%), were severely affected by hemophilia (77.5%) and 15% had inhibitors. Reliability estimation showed high internal consistency of total score with Cronbach’s α = 0.97, and for 2 summary scores ‘FREQUENCY’ with α = 0.95 and ‘BURDEN’ α = 0.92, Cronbach’s α for the sub domains ranged from α = 0.77 to 0.93. HEMOCABTM revealed good convergent validity with EQ-5D (Pearson’s r = 0.75). Concurrent validity showed significant differences in all domains of HEMOCABTM, except for ‘school’ among caregivers of CWH with inhibitors vs. without. Type of treatment and disease severity showed some differences between groups. Based on item and scale analysis 49 items were deleted and the final HEMOCABTM consists of 59 items.

CONCLUSIONS: HEMOCABTM is the first hemophilia-specific instrument for the assessment of caregiver burden and revealed good psychometric characteristics in terms of reliability and validity.

PRM81

USING THE CLINICAL SUMMARY SCORE FROM THE KANSAS CITY CARDIOMYOPATHY QUESTIONNAIRE AS AN ENDPOINT IN CLINICAL TRIALS: PSYCHOMETRIC SUPPORT

Objective: Symptoms and physical limitations can have an important impact on the day to day lives of heart failure patients. The Clinical Summary Score (CSS) of the Kansas City Cardiomyopathy Questionnaire was used to evaluate short- and long-term changes in patients. The present study included patients from 3 clinical trials. The CSS was sensitive to changes in patient status over time, as indexed by changes in the CSS. The CSS was sensitive to changes in patient status over time, as indexed by changes in the CSS. A24

PRM82

VALIDATION OF THE U.S. POPULATIONNORMALS OF HEALTH-RELATED PRODICTIVITY QUESTIONNAIRE

Objective: To validate the Health-Related Productivity Questionnaire (HRPQ), a new health-related productivity instrument, and estimate the US population

PRM83

MEASURING UPPER LIMB FUNCTION IN MULTIPLE SCLEROSIS: ENHANCING THE ABILHAND’S PERFORMANCE

Objective: Patient-reported outcomes (PROs) are necessary to assess disease impacts from the patient’s perspective. In line with the Food and Drug Administration’s (FDA) guidance on Patient-Reported Outcome (PRO) measures, the Dependent Family Functioning Scale (DFFS) was developed to assess the impact of major depressive disorder (MDD) on family functioning. Psychometric analyses were conducted to establish the measurement properties of DFFS according to the FDA PRO guidance. METHODS: Data from PERFORM, a longitudinal multicenter, prospective, observational, 2-year observational study in the United Kingdom and Spain, were analyzed (Nbaseline=478; NMfollow-up=433). The 15 DFFS items use a 5-point rating scale to assess partner and family interactions and quality of relationships, higher scores indicate higher quality of relationships. Test-retest reliability (intraclass correlations), construct validation (correlations and factor analysis), discriminant validity (analyses of variance), and responsiveness (effect size estimates) were evaluated. RESULTS: Factor analyses resulted in a single factor, confirmed by highly satisfactory Cronbach’s alphas (0.85 at baseline, 0.89 at month 2) The DFFS demonstrated satisfactory test-retest reliability (intraclass correlation=0.75). Hypothesized correlations with other measures provided evidence of convergent and divergent validity. For example, the correlation of the DFFS with SF-12 mental component scores was 0.35 (baseline) –0.49 (month 2), and with SF-12 physical component scores, 0.05 (baseline) and –0.31 (month 2). Hypothesis tests were generally in the predicted direction and many were statistically significant, substantiating the discriminant validity of the DFFS. Effect size estimates of responsiveness were 0.44–0.84, demonstrating that the items were capable of detecting change. CONCLUSIONS: The psychometric analyses strongly support the reliability, validity, and responsiveness of the DFFS and its usefulness for assessing the impacts of depression on family functioning. It has the potential to provide important information not traditionally captured in clinical practice or research and will facilitate a more comprehensive evaluation of treatments of MDD.

PRM84

VALIDATION OF THE DEPRESSION AND FAMILY FUNCTIONING SCALE (DFFS)

Objective: Patient-reported outcomes (PROs) are necessary to assess disease impacts from the patient’s perspective. In line with the Food and Drug Administration’s (FDA) guidance on Patient-Reported Outcome (PRO) measures, the Dependent Family Functioning Scale (DFFS) was developed to assess the impact of major depressive disorder (MDD) on family functioning. Psychometric analyses were conducted to establish the measurement properties of DFFS according to the FDA PRO guidance. METHODS: Data from PERFORM, a longitudinal multicenter, prospective, observational, 2-year observational study in the United Kingdom and Spain, were analyzed (Nbaseline=478; NMfollow-up=433). The 15 DFFS items use a 5-point rating scale to assess partner and family interactions and quality of relationships, higher scores indicate higher quality of relationships. Test-retest reliability (intraclass correlations), construct validation (correlations and factor analysis), discriminant validity (analyses of variance), and responsiveness (effect size estimates) were evaluated. RESULTS: Factor analyses resulted in a single factor, confirmed by highly satisfactory Cronbach’s alphas (0.85 at baseline, 0.89 at month 2) The DFFS demonstrated satisfactory test-retest reliability (intraclass correlation=0.75). Hypothesized correlations with other measures provided evidence of convergent and divergent validity. For example, the correlation of the DFFS with SF-12 mental component scores was 0.35 (baseline) –0.49 (month 2), and with SF-12 physical component scores, 0.05 (baseline) and –0.31 (month 2). Hypothesis tests were generally in the predicted direction and many were statistically significant, substantiating the discriminant validity of the DFFS. Effect size estimates of responsiveness were 0.44–0.84, demonstrating that the items were capable of detecting change. CONCLUSIONS: The psychometric analyses strongly support the reliability, validity, and responsiveness of the DFFS and its usefulness for assessing the impacts of depression on family functioning. It has the potential to provide important information not traditionally captured in clinical practice or research and will facilitate a more comprehensive evaluation of treatments of MDD.