DEVELOPMENT OF A CLASSIFICATION SYSTEM FOR A DIABETES-SPECIFIC PREFERENCE-BASED MEASURE OF HEALTH

Sundaram M, Smith MJ, Nath C
West Virginia University, Morgantown, WV, USA

OBJECTIVE: To develop a classification system (CS) for a diabetes-specific preference-based measure of health (PBMH).

METHODS: Plausible attributes for the PBMH were identified by Classical Test Theory, using Factor Analysis of responses from Type 2 Diabetes patients (n = 385) to the 18-item Audit of Diabetes-Dependent Quality of Life (ADDQoL). A seven-member expert panel then provided qualitative input for content. Three pilot rounds in outpatient and community settings produced data from people with Type 1 and Type 2 diabetes (n1 = 52, n2 = 65, n3 = 111) that were analyzed using Modern Test Theory, based on Rasch Analysis (RA), for 1) fit of selected attributes to the Rasch Model, and 2) scaling of severity levels for attributes. RESULTS: Principal Axis Factoring with Promax rotation identified two plausible attributes from six ADDQoL items. In a structured survey, experts rated the importance of all ADDQoL and additionally important items, and suggested attributes that might be described using sets of related items. A CS was developed consisting of five independent attributes, with each question containing a description based on the item content of the respective attribute and four sentences describing severity levels. Maintaining this format, the wording in the CS was further modified based on additional input from experts and RA after each pilot. The final attributes were: Physical Ability & Energy, Relationships, Mood & Feelings, Enjoyment of Diet, and Satisfaction with Management of diabetes. Results of the third pilot indicated Infit and Outfit MNSQ for the five attributes ranging between 0.88 and 1.10. Person and Item reliabilities were 0.63 and 0.92, while the respective separation ratios were 1.36 and 3.34. Severity levels used were supported by Rating Scale Diagnostics indicated by RA. CONCLUSION: Results of the statistical analyses indicate that the PBMH has desired psychometric properties. Research on the estimation of a utility scoring algorithm and validation testing of this PBMH is ongoing.
topics, understandability, and feasibility of use. Based on the above, a preliminary instrument was created for validation testing. RESULTS: Key themes generated from literature, clinician, and families included various aspects of pain, difficulty using the device, embarrassment, and time involved affecting productivity, convenience, and compliance. Two versions of the preference instrument were created to reflect the child and parent perspectives. A 4-point Likert scale was used for most questions. The child version included 38 survey items on clarity of instructions (2), preparation (7), administration (4), convenience (3), pain (5), embarrassment (2), anxiety (2), productivity (4), compliance (3), mood (1), and overall satisfaction (5). All items from the child questionnaire were included in the parent version, supplemented with five questions regarding administration, parent productivity, and parent overall satisfaction. CONCLUSION: Areas of concern for families using GH delivery devices include pain, productivity, and convenience. This new instrument, which may offer clinicians and researchers an opportunity to evaluate different device alternatives for GH replacement therapy, will soon undergo formal validation testing.

ASSOCIATION BETWEEN THE DIABETES-39 (DM-39) AS A PATIENT REPORTED OUTCOME (PRO) AND HbA1c IN A CLINICAL TRIAL INVOLVING INSULIN THERAPY

Lee L1, Hayes RP2, Heilbers L2, Jeziorowski J1, Sun P1, Beusching DP3
1 Eli Lilly and Company, Indianapolis, IN, USA; 2 Omnicare Clinical Research, King of Prussia, PA, USA; 3 Kailo Research Group, Indianapolis, IN, USA

OBJECTIVE: To assess the association between the DM-39 and HbA1c in a large insulin clinical trial (acronym: DURABLE) where HbA1c is a primary efficacy endpoint. METHODS: The DURABLE trial enrolled insulin-naïve type 2 diabetes patients and randomized them to lispro mix 75/25 bid or glargine q.d. Trial participants completed the DM-39 at baseline prior to receiving insulin. The DM-39 is a 39-item diabetes-specific PRO measure with 5 domains: Energy/Mobility (15-item), Diabetes Control (12-item), Anxiety/Worry (4-item), Social Burden (5-item), and Sexual Function (3-item). Each domain’s score ranged from 0–100 with a higher score representing worse PRO. We used Spearman’s correlation to assess the overall association with HbA1c. We also conducted analysis of variance (ANOVA) with pairwise comparisons using Scheffe adjustment to compare the mean scores reported by patients with baseline HbA1c <8.0% (group A); 8.0–8.9% (B); 9.0–9.9% (C); and >10% (D). RESULTS: A trial subgroup of 867 patients (mean age = 56.8 years, duration of diabetes = 9.6 years, HbA1c = 8.9%, 42% female, 65% Caucasian) provided the data. Correlations with HbA1c were low (r range: 0.01–0.18) with Diabetes Control (r = 0.18), Anxiety/Worry (r = 0.10), and Social Burden (r = 0.11) resulting in statistically significant correlations (p < 0.01). Overall ANOVA p-values were statistically significant for Diabetes Control (mean scores for groups A, B, C, and D = 37.5, 39.7, 43.7, and 46.2, respectively, p < 0.001), Anxiety/Worry (41.5, 42.2, 48.5, and 47.0, p = 0.003); and Social Burden (22.2, 21.6, 25.5, and 28.3, p < 0.001). Pairwise comparisons were statistically significant for Diabetes Control (A vs. C, A vs. D, and B vs. D); Anxiety/Worry (A vs. C); and Social Burden (A vs. D and B vs. D). CONCLUSION: DM-39 is weakly associated with HbA1c. However, our findings suggest that some targeted domains (e.g., Diabetes Control) may be useful in assessing the changes in PRO for clinical trials evaluating insulin initiation with a primary endpoint of HbA1c.