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WITHDRAWN

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

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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 each ADDQoL item. 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 0.65 and 0.92, while the respective separation ratios were 1.36 and 3.34. Severity levels were used 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.

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CONTENT DEVELOPMENT FOR A NEW INSTRUMENT TO ASSESS PATIENT AND PAREN'T PREFERENCE FOR GROWTH HORMONE REPLACEMENT THERAPY DELIVERY DEVICES

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OBJECTIVE: Few patient-reported outcome measures for growth hormone (GH) replacement therapy have been formally validated and none address preference for a particular delivery method. Our objective was to formally develop a new instrument to assess child and parent satisfaction with and preference for GH therapy delivery devices. METHODS: An instrument item pool was generated by combining the following four steps: 1) thorough literature review to identify relevant domains and questions, 2) consultation with clinicians knowledgeable about treatment of GH deficiency, 3) identification of indicators specific to GH delivery devices, and 4) input from families with children aged 10–16 years receiving GH therapy, including both new (2 to 12 weeks) and established (>12 weeks) users. Structured feedback forms were completed during cognitive interviews with focus groups on relevance of questions, missing

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PREFERENCES FOR ORAL ANTIDIABETIC AGENTS AMONG PEOPLE WITH TYPE 2 DIABETES

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OBJECTIVE: The objective of this study is to quantify the strength of preferences and likely adherence to therapy of people with type 2 diabetes mellitus (T2DM) for outcomes of oral antidiabetic agents (OADs). METHODS: Currently many of the available OADs for T2DM are associated with side effects such as weight gain and nausea and vomiting. Understanding patient preferences for medications with different attributes is important for predicting likely adherence to OAD treatments with different side effects. We developed a web-based instrument to elicit treatment preferences. Inclusion criteria were people 18 years of age and older who were insulin-naive and currently taking OADs to treat T2DM. The instrument included ten stated-choice trade-off tasks. Subjects chose between pairs of hypothetical medication alternatives, each including change in HbA1c levels, number of mild-to-moderate hypoglycemic events per month, water retention, weight gain in the first six months of treatment, mild stomach upset, and risk of heart attack. Sample sizes were 200 in the United States and 200 in the UK. RESULTS: The majority of subjects were white, married, and female. Subjects were willing to make tradeoffs between all medication attributes. On average, subjects would accept significant weight gain if the medication yielded a reduction in HbA1c that resulted in optimal control (6.5%). However, subjects’ stated adherence was significantly lower for treatments with weight gain, increased heart-attack risk, or persistent nausea and vomiting. The UK sample was less tolerant of hypoglycemic events. CONCLUSION: While people with T2DM believe glucose control is important, medication side-effects influence patients’ treatment choices. Efficacy as measured under controlled, clinical-trial conditions may overstate actual treatment effectiveness as a result of patient concerns over OAD side effects.