

glycemic control. To further improve outcomes for employees with diabetes and improve long-term cost-savings, employers might need to focus on programs that target medication adherence.

PDB45

ASSESSING UTILITIES AND DISUTILITIES FOR TYPE 2 DIABETES TREATMENT-RELATED ATTRIBUTES IN AN ASIAN POPULATION

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OBJECTIVES: To elicit utility values associated with type 2 diabetes from Korean and Taiwanese populations and identify key drivers of preferences within these populations. Utility studies conducted in non-Asian populations often elicit preferences using a survey population or scaling method that is not preferred by Asian payers. As the use of pharmacoeconomics becomes more prevalent in Asia there is a greater need to understand implications of adapting overseas studies and to identify appropriate utility values when calculating cost utility ratios in the region. **METHODS:** A total of 132 study participants (67 from the general population and 65 type 2 diabetes patients) were recruited equally from Korea and Taiwan. Health states for type 2 diabetic patients were adapted from a published UK study. Utilities for the health states were elicited using a chained standard gamble method (SG) and the EQ-5D. A paper SG was administered with multiple researchers assisting and verifying respondents' logic. Demographic data were collected. Analyses were conducted using approved methods and compared to published UK utility values. **RESULTS:** The mean utility of type 2 diabetes patients without complications was 0.937 (EQ-5D among patients). Asian patients indicated greater disutility from weight gain (-0.0488 for 5% gain) and less utility from weight loss (0.0184 for 5% loss), which was similar to findings from the UK. The average disutility associated with gastrointestinal side effects was -0.07. **CONCLUSIONS:** Localized utility studies provide insight into the geographical preferences related to type 2 diabetes health states. The value placed upon weight loss versus weight gain, a respondent's baseline BMI and differences in study design may drive variation in utilities between Asia and the UK. The ability to adapt utility studies conducted overseas to capture Asian preferences using methods preferred by Asian payers has meaningful implications for future cost utility studies conducted in Asia.

UTILITIES FOR INFUSION THERAPY IN TYPE 1 DIABETES

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OBJECTIVES: Recent advances in monoclonal antibody therapies offer the prospect of the prevention or amelioration of type 1 diabetes (T1DM). The present study was designed to capture UK preference weights for outcomes of infusion therapy for children (8–12yrs); adolescents (13–17yrs) and adults. Such values could be used in a cost effectiveness analysis. **METHODS:** In-depth interviews were conducted with adults (n = 4) and parents of children (n = 4) and parents of adolescents (n = 4) all with T1DM to characterise their quality of life. These data, plus an interview with a clinical expert and findings from a literature review were used to construct vignette descriptions of health. Vignettes described T1DM; T1DM with reduced need for insulin; T1DM insulin free; receiving infusion therapy and receiving infusion therapy plus acute phase reaction (APR). Separate vignettes described adults, adolescents and children. Following expert review of content validity, vignettes were rated (using the standard gamble interview) by the general public, adults with T1DM and parents of children with T1DM. Participants also the EQ-5D, PedsQL, and Hyperglycemic Fear Survey (data will be reported). Mixed model analyses were used to estimate the influence on utility of different participant characteristics. **RESULTS:** Each health state was a significant predictor of utility. The general public gave significantly different utilities to the T1DM participants ($p < .02$). The utility gain associated with successful treatment was greater for the public versus T1DM group (reduced insulin +0.026 vs +0.021, insulin-free +0.073 vs +0.057) and the disutility greater for undergoing infusion therapy (on-infusion -0.114 vs -0.093, on-infusion with APR -0.159 vs -0.131). **CONCLUSIONS:** The general public and people with diabetes (or parents of children) all place significant value on reducing the need for insulin injections, whilst recognising the disutility of undergoing infusion-based therapies. The differences between these groups may reflect adjustment and coping.

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HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH TYPE 2 DIABETES OVER THE 24 MONTHS FOLLOWING INITIATION OF INSULIN

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OBJECTIVES: To investigate health related quality of life (HRQL) using EuroQol EQ-5D in patients with type 2 diabetes over the 24 months following insulin initiation. **METHODS:** INSTIGATE is a European prospective observational study investigating patients with type 2 diabetes initiating insulin during usual care. Follow-up data on resource use, treatment, clinical and patient reported outcomes over the 24 months following insulin initiation were collected in Germany, Greece and Spain (N = 564).

RESULTS: Mean (SD) HbA1c was 9.4(1.72)% at insulin initiation, 7.2(1.03)% after 6 months, and 7.2(1.07)% after 24 months. Only in Germany did mean HbA1c fall below 7%. Treatment approach varied; at baseline in Germany patients were prescribed more intensive insulin regimens (mean 3.1 injections/day). In Greece and Spain most patients were prescribed either basal-only or premix-only with fewer mean daily injections (1.8 and 1.4 respectively). Across all patients at baseline, 14.5% reported problems with the EQ-5D self-care dimension, 37.9% reported problems with mobility and 31.4% with usual activities. In Greece, 68% of patients reported problems with anxiety/depression (overall: 54.1%); in Germany, 63% reported problems with pain/discomfort (overall: 52.3%). In the five dimensions, 62.4–80.3% of patients reported no change between baseline and 24 months, 10.4–16.1% reported worsening problems, and 8.6–22.9% reported improvement. Mean(SD) baseline EQ-5D visual analogue scale scores (VAS) were: Germany 65.7(19.07), Greece 64.8(19.24), Spain 63(18.32). Patients in Greece saw the greatest and most sustained improvement in VAS; mean increase from baseline to 6 months 13.9(15.08) and baseline to 24 months 11.9(17.82). In Germany and Spain increases from baseline to 6 months were 12.4(16.5) and 4.6(17.69) respectively. From baseline to 24 months there was an increase of only 6.1(18.86) in Germany and 6.7(20.83) in Spain. **CONCLUSIONS:** Following insulin initiation there was an increase in HRQL (VAS) through 6 months, although this appeared to diminish between 6 and 24 months.

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ASSESSING THE MINIMUM CLINICALLY IMPORTANT DIFFERENCE OF THE WORRY SCALE OF THE HYPOGLYCAEMIA FEAR SURVEY IN PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: To explore the concept of the Minimum Clinically Important Difference (MID) of the Worry Scale of the Hypoglycaemia Fear Survey (HFS-II) and to quantify the clinical importance of different types of patient-reported hypoglycaemia. **METHODS:** An observational study was conducted in Germany with 392 patients with type 2 diabetes mellitus treated with combinations of oral anti-hyperglycaemic agents. Patients completed the HFS-II, the Treatment Satisfaction Questionnaire for Medication (TSQM), and reported on severity of hypoglycaemia. Distribution- and anchor-based methods were used to determine MID. In turn, MID was used to determine if hypoglycaemia with or without need for assistance was clinically meaningful compared to having had no hypoglycaemia. **RESULTS:** 112 patients (28.6%) reported hypoglycaemic episodes, with 15 patients (3.8%) reporting episodes that required assistance from others. Distribution- and anchor-based methods resulted in MID between 2.1 and 5.8 and 3.6 and 3.9 for the HFS-II, respectively. Patients who reported hypoglycaemia with (21.6, 95% confidence interval (CI) 15.1; 28.1) and without (12.1, 95% CI 9.7; 14.5) need for assistance scored higher on the HFS-II (range 0 to 72) than patients who did not report hypoglycaemia (6.0, 95% CI 5.0; 7.0). **CONCLUSIONS:** We provide MID for HFS-II. Our findings indicate that the differences between having reported no hypoglycaemia, hypoglycaemia without need for assistance, and hypoglycaemia with need for assistance appear to be clinically important in patients with type 2 diabetes mellitus treated with oral anti-hyperglycaemic agents.

PDB49

UNDERSTANDING AND ASSESSING THE IMPACT OF GROWTH HORMONE DEFICIENCY IN ADULTS

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OBJECTIVES: Adult Growth Hormone Deficiency (AGHD) is a poorly understood disease. As a result, treatment patterns and health care access vary by country and misunderstandings regarding the patient reported impacts are common. A well developed PRO measure identifying disease and treatment issues for this population and sensitive to treatment effects is critical for future research and clinical decision making. The purpose of the study was to understand the full spectrum of PRO issues in AGHD and develop a validation ready measure of these impacts. **METHODS:** As the first phase of the PRO measure development process, qualitative data was collected from the literature, experts and patients and transcripts thematically coded according to grounded theory. Based on a synthesis of all information, a conceptual model of the impact of disease and treatment was developed and a PRO measure generated. **RESULTS:** 39 AGHD patients (7 focus groups, 3 telephone interviews) and 6 clinical experts in three countries (US, UK, Germany) were interviewed regarding the impact of AGHD and treatment on functioning, well-being and treatment burden. The mean age of patients was 50.7(range 23–82), mean age at diagnosis of 39.7 (range 4–71) and 87% were currently on treatment. Across countries common impacts were identified in the domains of Energy, Physical Health, Psychological Health, Cognition and Treatment Burden. A conceptual model of the impacts of AGHD, their consequences and modifiers to the relationship was developed and a 46 item PRO impact measure (TRIM-AGHD) was generated with 5 discrete domains. The TRIM-AGHD was then cognitively debriefed in 9 patients and a validation ready version created. **CONCLUSIONS:** The instrument development process, the full conceptual model, and discussion of clinical implications will be presented. This information should help clinicians identify key PRO issues for AGHD, facilitate targeted treatments and allow for meaningful measurement of treatment effect.