25 and the SF-36. Psychometric analyses of baseline data examined internal consistency (Cronbach's alpha), criterion validity (Spearman correlations), and discriminant validity of the VFQ-25. **RESULTS:** The 684 enrolled patients were primarily Caucasian (77.8%) and male (63.3%), with a mean age of 59.3 years. Cronbach's alphas for VFQ-25 scales indicated good internal consistency, ranging from 0.72 to 0.93 for all subscales except two 2-item subscales, which had alphas of 0.68 (ocular pain) and 0.64 (social functioning). The VFQ-25 demonstrated convergent validity through statistically significant correlations with SF-36 subscales. For example, correlations of the VFQ-25 role difficulties subscale with the eight SF-36 subscales ranged from 0.25 to 0.35 (all $p < 0.0001$). VFQ-25 subscales significant discriminated among groups of patients differing in ETDRS visual acuity scores (e.g., total VFQ-25 score = 79.1 for patients with ETDRS score of 48–78 letters; 83.0 for patients with 79–84 letters; 89.0 for patients with 85–100 letters). **CONCLUSION:** The VFQ-25 demonstrated adequate internal consistency reliability, criterion validity, and discriminant validity. Results support the use of this instrument among patients with diabetic retinopathy.

PDB34

EFFECT OF INSULIN GLARGINE AND NPH INSULIN ON QUALITY OF LIFE IN PATIENTS WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: Intensive treatment to achieve targeted glycemic index(HbA1c <7% and FBG <140 mg%) with the help of early initiation of basal insulin secretion in addition to oral hypoglycemic agents has been proposed for type 2 diabetes mellitus. Insulin glargine has been reported to be as efficacious as NPH insulin along with oral hypoglycemic agents in type 2 diabetes mellitus. However, its impact on quality of life has not been evaluated. **METHODS:** Forty patients of type 2 diabetes mellitus on two or more oral hypoglycemic agents for more than three months and unable to achieve targeted glycemic index were enrolled and randomized in a open label comparative trial into two groups, 20 patient each, taking either insulin glargine or NPH insulin in combination to previous treatment. The end points evaluated were glycemic index, hypoglycemic episodes impact on treatment satisfaction, well being and quality of life. **RESULTS:** Both the treatment groups equally achieved euglycemic levels. The mean decrease in HbA1c levels in both groups was the same but more number of patients (15 vs. 10) were able to achieve fair to good glycemic control in Insulin glargine group. Total episodes of hypoglycemia were 50% lesser in insulin glargine group (13 vs. 26) with no severe and lesser nocturnal episodes. Quality of life parameters improved in both groups but were significantly higher in insulin glargine group (treatment satisfaction: 43.75 ± 2.05 vs. 34.44 ± 1.68; General well being: 27.1 ± 2.37 vs. 16.75 ± 1.58; Total satisfaction: 35.50 ± 2.25 vs. 23.81 ± 1.92). Higher number of people had overall good to excellent rating of quality of life (18 vs. 10). **CONCLUSION:** Achievement of target glycemic control was similar in both insulin regimens however; patients on insulin glargine had significantly lesser number of hypoglycemic episodes and far better treatment satisfaction, Sense of well being and quality of life.

PDB35

ESTIMATING HEALTH-RELATED QUALITY OF LIFE FROM HYPOGLYCEMIA ELICITED FROM NON-DIABETIC AND DIABETIC RESPONDENTS IN CANADA

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OBJECTIVES: Hypoglycemia presents a challenge for patients using insulin. The fear and anxiety related to hypoglycemic episodes may inhibit intensified insulin treatment and cause patients to reduce driving, limit social activities and eat snacks. However, published estimates of health-related quality of life values (utilities) for hypoglycemia have been based on database studies and not directly measured in interviews. Our objective was to elicit societal and patient utilities in Canada for five health states including: diabetes, rare (quarterly), intermittent (monthly), frequent (weekly), and nocturnal hypoglycemia episodes. **METHODS:** The health state descriptions were based on the validated Hypoglycemia Fear Survey and the opinions of four experts. Time trade-off (TTO) interviews were used to elicit utilities from 79 non-diabetic and 50 diabetic respondents in Canada. The TTO method estimates utilities between 0 and 1, where 1 expresses full health and 0 represents dead. Interviewers used a TTO board that allowed respondents to trade between zero and 30 years of perfect health against 30 years in each health state. **RESULTS:** The diabetes health state was estimated at 0.92 (SD 0.13) and 0.88 (SD 0.13) by diabetics and non-diabetics, respectively. The disutility was greater with increasing hypoglycemia: rare episodes ranged from –0.01 to –0.03 in the two groups; intermittent –0.05 to –0.11; frequent –0.17 to –0.22; and nocturnal –0.12 to –0.17. In both groups, the disutility of nocturnal hypoglycemia was intermediate between intermittent and frequent rates hypoglycemia. **CONCLUSION:** Rare hypoglycemia episodes occurring only a few times a year, was rated as having only a minimal impact, whereas frequent episodes and nocturnal hypoglycemia had substantial impacts. This study is the first to directly estimate utilities for hypoglycemia, incorporating appropriately developed health states, using direct elicitation techniques, and including diabetic and non-diabetic respondents.

PDB36

DIFFERENCES IN EQ-5D SCORES FOR US AND UK-BASED PREFERENCE SCORING SYSTEMS IN PEOPLE WITH TYPE 2 DIABETES MELLITUS

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OBJECTIVES: This study reports differences in utility scores obtained using the U.S. and U.K. valuations of the EQ-5D in a cross-sectional study among patients with type 2 diabetes mellitus (T2DM). **METHODS:** Patients with T2DM at the outpatient clinics of a university hospital completed the EQ-5D. Health state preference scores were obtained using both the US and UK valuation systems of the EQ-5D, and matched with retrospective data including A1C, co-morbidities, diabetes-related complications, and BMI from electronic records and with self-report of insulin use and depressive symptoms (using the Center for Epidemiologic Studies—Depression). Paired sample t-tests assessed overall differences in US and UK scores. Using EQ-5D scores as the dependent variable, OLS regressions assessed the significance of diabetes-related complications and co-morbidities as predictors (dichotomized) individually; these were also preformed using US-UK difference scores as the dependent variable.

RESULTS: Usable response rate was 37% (n = 363). Mean A1C was 7.2 (SD 1.4), mean diabetes duration was 10.2 (SD 9.1) years, 62.1% were obese (BMI >30), and about 42% used insulin. Mean (SD) and range of EQ-5D index scores were: 0.71(0.21), –0.04 to 1.00 for the US; 0.60(0.32), –0.48 to 1.00 for the UK. Spearman's correlation between US and UK scores was 0.998 ($p < 0.001$). A paired samples t-test indicated that the US valuations were significantly higher ($p < 0.001$) with the mean difference being 0.11(0.11). In individual OLS regressions, those with neurological complications, ischemic heart disease, obesity or depressive symptoms had significantly higher EQ-5D US scores as well as UK scores. These conditions also significantly predicted greater differences between US and UK scores. **CONCLUSION:** Although well correlated, the U.S population means were significantly higher than UK population means, and this difference was seen across clinically relevant categories in T2DM. The preference scoring system employed may therefore influence results of research conducted using the EQ-5D instrument to measure preferences.

ENDOCRINE DISORDERS—Patient-Reported Outcomes

PEN1

ESTIMATING THE QALY BENEFITS OF TREATMENT FOR GROWTH HORMONE DEFICIENCY (GHD) IN ADULT PATIENTS: A PRECURSOR TO COST-EFFECTIVENESS ANALYSIS

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OBJECTIVES: Regulatory agencies demand QALYs as evidence of effectiveness in economic evaluation. This is a challenge for clinical studies in which outcomes are measured using condition-specific instruments that lack the required measurement properties. This study aims to provide a model for deriving EQ-5D utilities directly from the QoL-AGHDA. These estimates were used to calculate QALY deficit and treatment effects in adults with GHD in relation to the general population values. **METHODS:** A UK postal survey captured QoL-AGHDA (a condition-specific measure for patients with GHD) and EQ-5D responses from a broadly representative sample of the general population (n = 921). These data were used to construct two-step regression model ($R^2 = 0.42$). In the first, TTO-weighted ED-$5D_{index}$ was the dependent variable and yes/no responses to all 25 QoL-AGHDA items were coded as dichotomous dummy variables (x_i). In the second step utilities were computed as follows: $\text{QoL-AGHDA}_{utility} = b_0 + c*age + \Sigma bi*x_i + e_i$. $\text{QoL-AGHDA}_{utility}$ at yearly visits for 894 UK patients followed in the KIMS database was computed using the same regression model. Subsequently the mean QALY over time were compared to baseline values and assessed in relation to the cross-sectional age/gender population values. **RESULTS:** Health related quality of life measured by $\text{QoL-AGHDA}_{utility}$ in patients prior to GH replacement differed significantly from age/gender-matched values in the general population (0.67 vs. 0.85, $p < 0.0001$). After the first year of treatment the deficit was reduced to –0.07. Despite a dramatic improvement during the first year of treatment, patients' health status remained significantly different from general population reference values ($p < 0.001$) over the course of their treatment. Nevertheless, a mean undiscounted gain from baseline of 0.32 QALYs was seen in the treated patients, corresponding to 0.08 QALYs per year. **CONCLUSION:** Estimates of treatment benefit for use in economic evaluation can be successfully derived from condition-specific measures.

MENTAL HEALTH—Clinical Outcomes Studies

PMH1

CHANGES IN COMORBIDITIES, MEDICATION USE AND TREATMENT COSTS AFTER DIAGNOSIS OF GENERALIZED ANXIETY DISORDER

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OBJECTIVES: To evaluate the impact of Generalized Anxiety Disorder (GAD) on diagnosed comorbidities, medication use and treatment costs. **METHODS:** Claims were drawn from PharMetrics Integrated Outcomes Database for 12-month prior and post the first GAD (ICD9-CM: 30002) diagnosis between Janaury 2003 and June 2004 (the diagnosis date as the index date). No GAD diagnosis 12-month prior the index date, 24-month continuous insurance eligibility and aged 18–64 were required. Changes in diagnoses of comorbidities, medication use patterns, and treatment costs between the year before and after the index date were examined. Comparison among subgroups of GAD patients with comorbid depression and pain was also investigated. Wilcoxon Signed Rank test and McNemar's test were used to examine pre-post differences for continuous and categorical variables, respectively. **RESULTS:** A total of 240,041 patients were included in this study. The mean age was 41.7 years old and 67% were female. After diagnosis of GAD, a significantly higher percent of patients were diagnosed with depression (44.4% vs. 30.9%, $p < 0.001$), dyslipidemia (24.0% vs.19.9%, $p < 0.001$), and diabetes (6.1% vs. 5.3%, $p < 0.001$) than before GAD diagnosis. The use of antidepressants increased from 42.3% to 56.8% ($p < 0.001$). Compared to the year prior to GAD diagnosis, total annual costs increased by $2034 ($p < 0.001$) driven mainly by increases of inpatient and outpatient costs ($285 and $773, $p < 0.001$, GAD only and increased merely $306 for GAD patients with depression while GAD patients with pain and those with both pain and depression increased by $2253 and $4665 (both $p < 0.001$), respectively. **CONCLUSION:** Diagnosis of GAD had significant impact on comorbidities, medication use and treatment costs. Furthermore, comorbid pain and depression had substantial extra burden on GAD patients as compared with those had GAD only. Recognizing these comorbidities is important in the treatment of patients with GAD.

PMH2

DIVALPROEX SODIUM VERSUS VALPROIC ACID: DRUG UTILIZATION PATTERNS, PERSISTENCE RATES, AND PREDICTORS OF HOSPITALIZATION AMONG VA PATIENTS DIAGNOSED WITH BIPOLAR DISORDER

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