iramate. Each patient also answered the Norfolk Quality of Life questionnaire for diabetic neuropathy (QOL-DN) before and after treatment. The QOL-DN questionnaire was used to assess the patients’ perception of the effects of diabetic peripheral neuropathy on their quality of life. RESULTS: Total QOL: before = 27.76 ± 5.40, after = 17.29 ± 4.66 (P = 0.00028). Small fiber: before = 2.35 ± 0.77, after = 1.59 ± 0.68 (p = 0.149). ADLs: before = 1.83 ± 0.74, after = 1.22 ± 0.69 (p = 0.276). Symptom Score: before = 8.28 ± 1.24, after = 3.39 ± 0.69 (p = 0.00004). Autonomic Function: before = 1.06 ± 0.47, after = 1.00 ± 0.47 (p = 0.834). Large Fiber: before = 15.06 ± 3.30, after = 10.01 ± 2.79 (p = 0.0044). Topiramate significantly improved 3 of the 5 domains of QOL-DN. There was a significant correlation between the changes in QOL symptom score and proximal leg cold sensation (r = 0.459, p = 0.0448). In addition, the correlation between changes in QOL large fiber neuropathy score and objective changes in Total Neuropathy Score approached significance (r = 0.439, p = 0.0637). Thus, topiramate improves objective indices of nerve function and QOL. CONCLUSIONS: Nerve Function improvement and enhanced QOL can be used as a measure of response to therapy in clinical trials.

**PDB36**

**EQ-5D IN TYPE 2 DIABETES: RELATIONSHIPS WITH QUALITY OF LIFE AND COMORBID CONDITIONS**

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**OBJECTIVES:** While measures of quality of life (QoL) have been widely used in patients with Type 2 diabetes mellitus (T2DM), there is insufficient data on preference-weighted health status measures like the Euroqol EQ-5D. This study reports statistical relationships among the EQ-5D and QoL measures, and with comorbid conditions like obesity and depression. **METHODS:** Patients with T2DM at the outpatient clinics of a university hospital completed a mailed questionnaire which included the EQ-5D and a variety of QoL measures. Results: Usable response rate was 44.3% (n = 385). Average EQ-5D score was 0.71 (±0.21). Spearman correlations with the EQ-5D index were: SF PCS-12 (0.640), SF MCS-12 (0.534), CES-D (−0.578), ADDQoL (0.316). Average EQ-5D scores were significantly lower for patients on oral medications and insulin (0.65 ± 0.22) compared to those only on oral medications (0.76 ± 0.19) (p < 0.001), and in those with at least one diabetes-related complication (0.68 ± 0.22) compared to those without (0.74 ± 0.21) (p = 0.011). There were no significant differences on the basis of glycemic control levels obtained from patients’ A1C. Approximately 86% of those reporting no anxiety and depression on the EQ-5D were classified as not having depressive symptoms on the CES-D (Chi Square = 144.6, p < 0.001; Somer’s d = 0.66, p < 0.001). Nearly 73% of patients reporting moderate problems with mobility and usual activities each on the EQ-5D were clinically obese. Simple linear regression indicated that the SF PCS-12 and SF MCS-12 together explained 57% of the variance in EQ-5D scores. **CONCLUSIONS:** EQ-5D scores reflected deficits in health status on the basis of diabetes severity variables like treatment type and diabetes-related complications, as well as conditions co-morbid to T2DM like obesity and depression.

**PDB17/DB1**

**PATIENT-REPORTED UTILITIES/DISUTILITIES ASSOCIATED WITH TREATMENTS FOR TYPE 2 DIABETES**

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It has been shown in the literature that quality of life differs by anti-diabetic treatment. **OBJECTIVE:** This study investigates salient differences between exenatide and insulin—products that show similar efficacy for the treatment of type 2 diabetes. Namely, compared with insulin, exenatide is associated with weight loss rather than weight gain and a higher incidence of nausea early in treatment. The current study used standard gamble (SG) methodology to estimate the utility/disutility of these attributes. **METHODS:** Hypothetical diabetes-related health states (with variations in nausea and weight) were created based on clinical trial data and the input of clinical experts and patients. Patients in Scotland and England with type 2 diabetes rated these health states and their own current health state in SG interviews. Patients completed the EQ-5D, PGWB, and the Appraisal of Diabetes Symptoms (ADS). Construct validity and health state differences were examined with correlations, t-tests, and ANOVAs. **RESULTS:** A total of 129 patients (51 Scotland; 78 England) completed standard gamble interviews. The mean utility of a health state at the patients’ current weight without nausea was 0.89. Higher weight was associated with lower utility, and lower weight was associated with higher utility (e.g., 5% higher weight = 0.83; 3% higher weight = 0.85; 3% lower weight = 0.91; 5% lower weight = 0.92). Differences between health states that varied by weight were statistically significant (e.g., current weight vs. 3% higher and 3% lower; both p < 0.001). Health states with nausea were rated significantly lower than otherwise identical health states without nausea (p < 0.001). SG ratings of own health (mean = 0.87) demonstrated construct validity through significant correlations with patient-reported outcome measures. **CONCLUSIONS:** Findings suggest that patient standard gamble interviews are a feasible method for obtaining utilities for type 2 diabetes utilities/disutilities. The utilities obtained in this study would be appropriate for use in a cost-utility analysis of treatment for type 2 diabetes.

**PDB38**

**A LITERATURE REVIEW OF TREATMENT SATISFACTION, ADHERENCE AND QOL INSTRUMENTS USED IN TYPE 1 AND 2 DIABETES**

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**OBJECTIVES:** To describe and compare the domains and psychometric properties of selected instruments used in diabetes Type 1 and Type 2. **METHODS:** A systematic literature review of published studies was conducted using MEDLINE (1990–2005), EMBASE (1990–2005) and the Mapi Research Trust databases. Only studies describing the development or use of a referenced instrument assessing QOL, treatment satisfaction or adherence in patients with diabetes type 1 or 2 were reviewed. Articles including diabetic patients after transplantation were not included. **RESULTS:** Thirty instruments were identified: four for patients under Insulin treatment (type 1 & 2), two for type 2 diabetes, nine “diabetes generic” (type 1 and type 2 treated with Diet or tablets and/or insulin), five for devices, three for adherence, two for diabetic complications, two were batteries and three were generic questionnaires. Out of these only nine had good psychometric properties. Three of them were fully validated, including responsiveness: the DQLCTQ for insulin-
treated patients, the generic SF-36 and DFS specific for patients with foot ulcers. Six other instruments were well validated and widely used, but their responsiveness was not documented and their sensitivity to change in RCTs was not consistent across the trials. CONCLUSIONS: Though several instruments have been identified, most of the them are specific for a subtype of diabetic population (type 1 or type 2, insulin-treated, patients with complications) and do not meet all criteria in regard to their psychometric properties. Further research is warranted to assess the sensitivity to change of diabetes specific patient reported outcomes instruments.

**PDB39**

**DIABETIC PATIENTS’ PREFERENCE FOR INHALED INSULIN**

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**OBJECTIVE:** Assessment of diabetic patients’ Willingness To Pay (WTP) for inhaled insulin in relation to injected insulin.

**METHODS:** A questionnaire concerning preference and WTP for inhaled insulin was completed by 157 patients (age range, 20–65 years) in Sweden. Type 1 diabetic patients were receiving treatment with insulin (n = 40) and Type 2 patients were receiving treatment with either insulin as single therapy (n = 21), a combination therapy with insulin and anti-diabetic drugs (n = 46), or an oral anti-diabetic treatment with at least 2 oral drugs (n = 50). Patients were asked to assess their WTP for inhaled insulin by choosing from eight comparisons, at different prices. A Conditional Logit model was used to estimate the utility as a function of treatment and price. The WTP measure were the incremental price patients were willing to pay for inhaled insulin compared to injected insulin. **RESULTS:** Patients were willing to pay an additional 400SEK [50 US dollars] per month (on average) for inhaled insulin in comparison to injected insulin. Type 1 patient reported a lower marginal WTP than Type 2 patients. Type 1 patients were willing to pay an additional 219 SEK. Type 2 patients on insulin as single therapy, or on a combination therapy with insulin and anti-diabetic drugs, or treated with an oral anti-diabetic treatment with at least 2 oral drugs were willing to pay additionally 375SEK, 381SEK, 667SEK, respectively. At equal prices (500SEK) a total of 129 patients (85%) preferred insulin inhalation. At a large price difference, (300SEK vs 1400SEK), only 16% preferred inhalations.

However, as many as 27 percent of patients on oral anti-diabetic drug treatment still preferred inhaled insulin. **CONCLUSION:** In comparison to injected insulin 85% of patients preferred inhaled insulin at equal prices and patients are on average willing to pay 400SEK per month.

**GI DISORDERS—Clinical Outcomes**

**PGI11**

**HEPATITIS B IMMUNISATION FOR NEWBORNS OF HEPATITIS B SURFACE ANTIGEN-POSITIVE MOTHERS: A COCHRANE HEPATO-BILIARY GROUP SYSTEMATIC REVIEW AND META-ANALYSIS**

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**OBJECTIVES:** To assess the beneficial and harmful effects of hepatitis B active immunisation (vaccines) and passive immunisation (immunoglobulins) for newborns of positive hepatitis B surface antigen (HBsAg) mothers. Trials were identified through the trial registers of The Cochrane Hepato-Biliary Group, The Cochrane Neonatal Group, The Cochrane Library, MEDLINE, EMBASE, authors of trials, and industry until February 2004. **RESULTS:** Compared with placebo/no intervention, hepatitis B immunoglobulins (HBIG) significantly reduced hepatitis B occurrences (RR 0.50, 95% CI 0.41 to 0.60). Compared with vaccination alone, vaccination plus HBIG significantly reduced hepatitis B occurrences (RR 0.54, 95% CI 0.41 to 0.73). HBIG significantly reduced hepatitis B occurrences if administered within 12 hours of birth, but not within 24 or 48 hours of birth. No significant difference on hepatitis B occurrence was found between recombinant vaccine (RV) or plasma-derived vaccine (PDV) (RR 1.00, 95% CI 0.71 to 1.42). No significant differences on hepatitis B occurrences were found between high-dose PDV and low-dose PDV (RR 0.97, 95% CI 0.53 to 1.68) or high-dose RV and low-dose RV (RR 0.78, 95% CI 0.31 to 1.94). Hepatitis B vaccines and HBIG seem generally safe, but few trials reported on adverse events. In general, methodological quality did not significantly influence the results. **CONCLUSIONS:** Hepatitis B vaccination and HBIG within 12 hours of birth significantly reduces hepatitis B occurrences in infants of HBsAg-positive mothers.

**PGI2**

**DOSE-RESPONSE RELATION OF INTERFERON-ALPHA IN PATIENTS WITH HBEAG-POSITIVE CHRONIC HEPATITIS B: META-ANALYSIS AND META-REGRESSION OF RANDOMIZED TRIALS**

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**OBJECTIVES:** To examine dose-response relation of interferon-α in patients with HBeAg positive chronic hepatitis B (CHB) and quantify the effect size of treatment in different regimens. **METHODS:** We searched Medline, SCI-expanded, Current Content Connect, Cochrane Library, and Chinese Biomedical Database to September 2005, and screened references of eligible studies. Randomized trials comparing interferon-α with non-antiviral interventions (placebo/no treatment/standard care) in patients with HBeAg-positive CHB were included. Heterogeneity was examined by the Q statistics and Galbraith plots. Meta-regression was used to analyze the relation of study characteristics to treatment outcomes. Fixed and random effect meta-analysis were used to pooled virological and serological response. When results differed in two models, random effect model was reported. **RESULTS:** Thirty-two trials were included (n = 2164). Dose of interferon-ranged from 1–10 MU, treatment duration ranged from 4–24 weeks, and length of follow-up varied from 12–130 weeks. Loss of HBeAg was responsive to dose (coefficient = 0.136, 95% CI = 0.028–0.28) and duration (coefficient = 0.076, 95% CI = 0.0048–0.15), while other outcomes were not. Stratified analyses showed that high-dose (≥ 5 MU) and regular duration (16–24 weeks) could effectively clear HBeAg (OR = 3.28, 95% CI = 2.31–4.66; OR = 3.28, 95% CI = 2.16–5.00), and clear HBV DNA (OR = 2.80, 95% CI = 2.03–3.86; OR = 2.58, 95% CI = 1.62–4.12). HBeAg seroconversion could be seen in all-dose groups (OR = 2.02, 95% CI = 1.37–2.97). The number-needed-to-treat for loss of HBeAg was four in high-dose and nine in low-dose treatment. Specifically, a high-dose and regular-duration of interferon-α was associated with significantly higher loss of HBeAg in Chinese patients (OR = 2.99, 95% CI = 1.53–5.87; OR = 2.56, 95% CI = 1.23–5.33), which otherwise was not effective in clearing HBV DNA. **CON-