medications, to assess its impact on healthcare costs, and to deduce areas for further research. METHODS: A systematic literature search (1990–2004) using an exhaustive list of relevant search terms was performed to identify articles with qualitative and quantitative data on adherence with oral anti-diabetic agents (OAs) and insulin. Studies describing the economic impact of non-adherence, including impact of medication co-payment on level of adherence, were also reviewed. Electronic Medline® and PubMed® searches along with manual review of bibliographies were conducted in different phases for article retrieval.

RESULTS: Adequate documentation of adherence and its economic impact was found in 51 studies. Most adherence studies were conducted on OAs. Thirty-seven retrospective studies showed that adherence to diabetes treatment ranged from 31% to 90%, mostly measured by medication possession ratio, with levels slightly lower among insulin patients. Results varied due to a diversity of applied methodologies, where definitions of compliance and persistence were calculated differently. Race, multiple dosing, mode of administration, and patients’ behavioral factors were significantly associated with adherence levels. Economic consequences of poor adherence were identified from seven studies (five retrospective, one patient survey, and one longitudinal cohort study), which demonstrated an increase in hospitalizations, premature disability, and other adverse events resulting in higher healthcare costs. Increasing co-payments (7 retrospective studies) resulted in a decrease in taking medications leading to increased adverse events and subsequent healthcare costs. CONCLUSIONS: This review confirms the lack of adequate treatment adherence among patients with diabetes and illustrates the considerable economic impact. More sophisticated methods of determining medication adherence have the potential to more accurately estimate adherence rates. Research demonstrating adherence to insulin therapies, particularly insulin pens, and related economic consequences are lacking in the literature.

PDB33
THE RELATIONSHIP BETWEEN HEALTH RELATED QUALITY OF LIFE (HRQOL) AND PAIN RESPONSE IN PATIENTS WITH DIABETIC PERIPHERAL NEUROPATHIC PAIN (DPNP)
McCrink L1, Beard S1, Le TK2
1RTI Health Solutions, Manchester, UK, 2Eli Lilly, Indianapolis, IN, USA

OBJECTIVE: The objective of this study was to investigate the association between pain response and health-related quality of life (HRQoL) in patients with diabetic peripheral neuropathic pain (DPNP).

METHODS: EQ-5D data was collected at baseline and endpoint in three large placebo controlled randomised trials which evaluated duloxetine treatment for DPNP over a 12-week horizon. Patients had a clinical diagnosis of pain due to bilateral peripheral neuropathy caused by diabetes, had a mean 24-hour average pain severity score ≥ 4 on the 11 point Likert scale (“0 = no pain” and “10 = pain as bad as you can imagine”) and suffered from daily pain for at least 6 months. Treatment response was based on the level of change observed in the average pain severity score. Three levels of clinically meaningful pain response were defined: full response (≥50% change in average pain severity), partial response (30 to 49% change average pain severity), and no response (<30% change in average pain severity). Utility data at the trial endpoint were pooled and stratified into the corresponding pain response thresholds.

RESULTS: Patients had pain and utility scores measured at baseline (n = 1139) and trial endpoints (n = 998) across the three randomised trials. The average pain score at baseline was 5.8 ± 1.5 with a corresponding utility score of 0.58 ± 0.26. At trial endpoint, patients in the no response to treatment category had lower utility scores (0.61 ± 0.24) compared to patients with either a partial response (0.70 ± 0.16) or full response (0.78 ± 0.16). In addition, a statistically significant negative correlation was found, indicating that increasing pain severity was strongly associated with lower HRQoL in DPNP patients.

CONCLUSION: Pain response had a considerable impact on HRQoL in DPNP patients. In addition, pain severity scores were significantly associated with lower HRQoL.

PDB34
HEALTH-RELATED QUALITY OF LIFE IN PATIENTS WITH DIABETES MELLITUS—TYPE 1 AND TYPE 2
Prucz C1, Suchdev S1, Jansson-Blitz C1, Toft E1
1Pfizer AB, Stockholm, Sweden, Sweden, 1Pfizer AB, Sollentuna, Sweden, Sweden, 3Pfizer AB, Sollentuna, Sweden, 4Ersta Sjukhus, Stockholm, Sweden

OBJECTIVE: This study aimed to estimate the health-related quality of life (HRQL) utility score for patients with diabetes mellitus Type 1 and Type 2 on insulin and/or oral treatment using EQ-5D and to compare differences in HRQL for controlled and uncontrolled patients.

METHODS: We surveyed 157 patients in a cross sectional study with treated Type 1 and Type 2 diabetes in Sweden (age range 20–65 years). Physicians recorded demographic and treatment information, including medications for diabetes. HRQL was measured using the EQ-5D questionnaire and was filled in by the patients at a physician visit. We evaluated the differences between groups (e.g. treatment regimes) using GLM-models. All statistical tests were performed at the 0.05-level of significance and were all two-sided. EQ-5D was linked to utility weights using an algorithm that converges ordinal ratings into a weighed composite score.

RESULTS: The mean utility score for the entire sample was 0.81 (SD 0.21) with a median of 0.79 (min –0.18, max 1.00). Patients with Type 1 diabetes had a higher mean utility score (0.88) than patients with Type 2 diabetes. Patients treated with a mixed regimen of oral antidiabetics and insulin reported a lower utility score (0.76). However, differences between treatment groups were not significant at the 5% level (p = 0.063). No significant difference was estimated in the health utility score for patients with controlled diabetes according to Swedish guidelines in comparison to uncontrolled patients. Women had significantly lower EQ-5D utility score than men, 0.76 and 0.85 respectively (p = 0.0217). The utility score ranged from 0.92 in the youngest age group (age 20–45) to 0.78 to the oldest age group (age 61–65) (p = 0.02).

CONCLUSION: Type 1 diabetes patients reported a higher HRQL than Type 2 diabetes patients. Women had significantly lower EQ-5D score than men.

PDB35
TOPIRAMATE TREATMENT IMPROVES QUALITY OF LIFE (QOL) AND NERVE FUNCTION IN PATIENTS WITH DIABETIC NEUROPATHY (DN)
Rice AL1, Vinken EJ1, Barlow PM1, Ford-Molvik SL1, Vinken AI1
1Eastern Virginia Medical School, Norfolk, VA, USA

OBJECTIVE: To test the hypothesis that improved nerve function using the anti-epileptic/migraine drug topiramate would translate to better quality of life (QOL). METHODS: Twenty patients with diabetic peripheral neuropathy were consented and entered into a study on topiramate. The dosage for each patient was titrated over a six-week period from 25 mg per day to 50 mg twice a day. The patients remained on 100 mg a day for 12 weeks and then were tapered off the medication over an additional 4-week period. Each patient received quantitative sensory testing, electromyography, skin blood flow, skin biopsies, and neurological examinations before and after treatment with top-