cohorts. Daily number of prescribed tablets whatever the therapeutic classes is significantly higher in the free cohort (6.4 per day vs. 3.1). An increase of 10% of the first treatment year, significantly more patients of the fixed cohort are still treated by the same association regardless daily doses or potential add-on treatments (85% vs. 72%, p<0.0001); moreover MPR is the same in both fixed and free cohort (64% vs. 62%).

**OBJECTIVES:** To compare the health related quality of life (HRQoL) in Polish patients with type 2 diabetes (T2D) and in matched sample from the general population. Time line from two non-interventional studies: prospective study of patients with T2D and EQ-SD Polish general population norms study Analysis of HRQoL was conducted in four separate age groups: 32–44, 45–54, 55–64, 65+ years. We analyzed an objective and objective HRQoL of HQR (EQ VAS and EQ-SD index) and the presence of restrictions within five dimensions of the EQ-5D descriptive part. RESULTS: A total of 274 patients with T2D and 214 representatives from population norms study were included. EQ VAS was systematically lower in diabetic patients compared to the general population, and decreased with age (68.2 vs 83.9, 64 vs 79.2; 54.9 vs 78.1, 50.2 vs. 69.8 in consecutive age groups). A similar relationship was observed with EQ-SD index. The largest mean differences were observed among age 55–64 years (EQ VAS: 23.2, EQ-SD index: 0.085). In three domains: self-care, usual activities and anxiety/depression, patients with diabetes above 45 years of age, reported significantly more problems than non-diabetic patients from the general population. CONCLUSIONS: The objective and objective HRQoL in patients with T2D is lower than in responders of similar age from the general population. Compared with type 2 diabetic populations from other countries, Polish patients characterize by a relatively high HRQoL objective and subjective HRQoL in patients with T2D is lower than in responders of similar age from the general population.

**DISCUSSION:** The impact of Type 2 diabetes mellitus (T2DM) on health related quality of life (HRQoL) is complex due to the burden of disease, lifelong treatment requirements and comorbidities. This study aimed to capture UK societal utility values for health states associated with T2DM and treatment-related adverse events (AEs) to assist stakeholders in the decision-making processes. Men and women had different HRQoL scores and age strata were developed (from a literature review and patient and clinician qualitative input) depicting the burden associated with T2DM and treatment related AEs. These were mild/moderate urinary tract infection (UTI); severe UTI; mycotic infection; moderate hypoglycaemic events; severe hypoglycaemic events, fear of hypoglycaemia, gastrointestinal symptoms; and hypervolaemic events. Members of the UK general public (n=100) valued these states using the time trade-off (TTO) method. The difference in mean utility values (between 0= dead, 1= full health) Regression analysis was conducted to understand influence of age and gender. RESULTS: All treatment-related AEs were found to have a significant effect on utility from the T2DM baseline state (0.90), the experience of AEs was associated with the following disutility: T2DM with hypervolaemic events (0.08), T2DM with mild/moderate UTIs (0.09), T2DM with moderate hypoglycaemic events (0.11); T2DM with severe hypoglycaemic events (0.15); T2DM with fear of hypoglycaemia (0.15); T2DM with severe UTIs (0.19); T2DM with GI symptoms (0.24); and T2DM with mycotic infection (0.25).

Males consistently scored the states with significantly lower utility values, but no significant age effects emerged. CONCLUSIONS: Findings suggest that adverse events in diabetes can be a burden for the disutility. The statistical importance of including information regarding AEs in economic evaluations. Although some states were rated severely in terms of utility, in reality, many of these only last a few days, therefore having a minimal quality adjusted life year (QALY) impact.

**PDB84**

**HEALTH-RELATED QUALITY OF LIFE AND UTILITY IN PATIENTS WITH DIABETIC FOOT ULCERS – AN EQ-SD SURVEY IN POLAND**

Sobota I*, Maciejczyk T*, Krakowiak A*, Mrozikiewicz-Rakowska B*, Mienicka A*, Młyńczak M*, Kasprzak M*, Pawełski J*, Karnawel W†, Hermanowski T†. 1Medical University of Warsaw Central Clinical Hospital, Warsaw, Warsaw, Poland

**OBJECTIVES:** To compare the health related quality of life (HRQoL) in Polish patients with type 2 diabetes (T2D) and in matched sample from the general population. Time line from two non-interventional studies: prospective study of patients with T2D and EQ-SD Polish general population norms study Analysis of HRQoL was conducted in four separate age groups: 32–44, 45–54, 55–64, 65+ years. We analyzed an objective and objective HRQoL of HQR (EQ VAS and EQ-SD index) and the presence of restrictions within five dimensions of the EQ-5D descriptive part. RESULTS: A total of 274 patients with T2D and 214 representatives from population norms study were included. EQ VAS was systematically lower in diabetic patients compared to the general population, and decreased with age (68.2 vs 83.9, 64 vs 79.2; 54.9 vs 78.1, 50.2 vs. 69.8 in consecutive age groups). A similar relationship was observed with EQ-SD index. The largest mean differences were observed among age 55–64 years (EQ VAS: 23.2, EQ-SD index: 0.085). In three domains: self-care, usual activities and anxiety/depression, patients with diabetes above 45 years of age, reported significantly more problems than non-diabetic patients from the general population. CONCLUSIONS: The objective and objective HRQoL in patients with T2D is lower than in responders of similar age from the general population. Compared with type 2 diabetic populations from other countries, Polish patients characterize by a relatively high HRQoL objective and very low subjective assessment.
OBJECTIVES: Foot ulceration is a major cause of disability in diabetes. The aim of the study was to identify influences of severity of diabetic foot ulceration on HRQol. METHODS: A survey among DFS (Diabetic Foot Syndrome) patients with active foot ulceration treated in ambulatory care was conducted. The PEDIS scale was used to classify severity of ulceration. To assess the impact of diabetic ulceration on daily life, the EQ-5D was used. Quality of life (QoL) was measured with the EQ-5D.

RESULTS: Between April 2012 and May 2013 185 patients were questioned directly. 179 of them (131 males) completed the EQ-5D questionnaire and had full record of ulceration severity (the PEDIS scale). The mean age of patients was 61.9±10.6 years. Diabetes type 2 was diagnosed in 150 (83.8%) patients while diabetes type 1 in 26 (14.5%). Other type of diabetes was diagnosed in 2 persons and data on one were missing. Mean time from the diagnosis of diabetes was 18.0±11.1 years. 99 (55%) and 64 (35.0%) patients had grade 1 and 2 perfusion, respectively. The mean ulceration size was 6.2±13.4 cm². 74 (41.3%), 65 (36.3%) and 40 (22.3%) patients had grade 1, 2 and 3 depth, respectively. 84 (46.9%) patients had grade 1 and 2, 1 and 3 infection, respectively. Most patients (89%) had loss of protective sensation (grade 2 sensation). Mean utility value in overall population was estimated at 0.618±0.320. Very weak negative correlation was found between ulceration size and utility values (p=0.001) with moderate-strong association between the total and/or subscale scores of the DPNPI measure and other logically related measures (range 0.43 to 0.79). Additionally, all a priori hypothesized associations for content and/or known group validity of domains and total score were confirmed (p<0.001) and IRT fit statistics were within acceptable range. CONCLUSIONS: The final 18-item version of the DPNPI was designed, valid and reliable measure of the impact of DPNP on patients’ daily lives and physical functioning. This measure can be used as an endpoint in clinical trials to assess impacts related to DPNP. Further study is needed to understand the responsiveness of the DPNPI.

PD89
HOW HYPOGLYCEMIA IMPACTS QUALITY OF LIFE AND TREATMENT SATISFACTION IN TYPE 2 DIABETES MELLITUS PATIENTS ON BASAL-BOLUS INSULIN THERAPY?

Moneta T1, Odin VP1, Nikitin TP1, Kurbatova KA1, Shakhlovskaia NE1

1 Multinational Center for Quality of Life Research, Saint-Petersburg, Russia, 2Military Medical Academy, Saint-Petersburg, Russia

OBJECTIVES: Hypoglycemia is the most common problem in patients with type 2 diabetes mellitus (T2DM) receiving insulin treatment. However, how hypoglycemia impacts the overall quality of life (QoL) and treatment satisfaction in T2DM patients is less clear. We aimed to study the QoL and treatment satisfaction in T2DM patients on basal-bolus insulin therapy with the absence and presence of different types of hypoglycemia. METHODS: A total of 500 T2DM patients receiving basal-bolus insulin therapy for at least 6 months were enrolled in the survey: male/female 122/378; mean (SD) age 61.8 (8.4) yrs; mean (SD) time from T2DM diagnosis 12.8 (6.9) yrs. Mean HbA1c level was 8.3%. Patients were classified as with no, non-severe, severe and nocturnal hypoglycemia events during the last month. Patients filled out SF-36 and Patient Treatment Satisfaction Questionnaire. The impact of hypoglycemia on QoL and treatment satisfaction was examined through multivariate regression, adjusting for sociodemographic and diabetes-related patient characteristics. Treatment satisfaction scores were analyzed using t-test, ANOVA, Chi-square test. RESULTS: After adjustment, QoL and treatment satisfaction decreased with the increase of hypoglycemia events (p<0.05). Patients who had significantly lower QoL scores for 6 out of 8 SF-36 scales as compared to those without hypoglycemia (p<0.05). Treatment satisfaction was higher in patients without hypoglycemia than in those with hypoglycemia (mean score 7.25 vs 8.0; p=0.01). Patients with nocturnal and severe hypoglycemia had significant reduction of role-physical, social functioning, vitality and pain as compared to patients with non-severe hypoglycemia (p<0.05). The percentage of patients who were completely dissatisfied or poorly satisfied with treatment was higher in the group with severe or/and nocturnal hypoglycemia than in those with non-severe hypoglycemia (20% vs 8%; p=0.002). CONCLUSIONS: Hypoglycemia has negative impact on QoL and treatment satisfaction in T2DM patients. Severe and nocturnal hypoglycemia significantly decreases QoL and reduces treatment satisfaction.