non-institutionalized population, was used. A total of 7396 adult diabetic patients were identified based on ICD-9-CM code of 250 after excluding pregnant women and cancer patients. These patients were classified as normal(body mass index-(BMI):18.5 –< 25), overweight(BMI:25 –< 30), or obese(BMI: ≥30). TCs included all costs except for treatment of dental problems or injuries. The impact of overweight/obesity on TCs at various points of the cost distribution was estimated using the weighted quantile regression model after adjusting for age, gender, and other study variables. The effects of the study variables on the median TCs were investigated using the weighted median regression. All costs were converted to 2005 U.S. dollars using price indices. Data were analyzed using SAS and SUDAAN. **RESULTS:** Compared with normal-weight patients, the incremental TC attributable to overweight were significantly higher from $238, $268, $409, and $442 at the 10th, 25th, 50th, and 75th percentile respectively. But incremental costs were diminished to $270 at the 90th percentile because of high costs in normal weight patients with severe comorbidities such as nephropathy. Similar trends were found in obese-patients compared with normal-patients, and attributable costs are bigger. Median TCs were increased in women vs. men and Caucasian vs. African-American, and as patients became older. **CONCLUSIONS:** The impact of overweight or obesity on TCs in diabetic patients was substantial especially in the lower tail of the TC distribution. The study findings suggest that controlling of weight to reduce TC is very important in most diabetic patients, but less important in the upper tail of the TC distribution. The quantile regression method is useful for estimating TCs at the different percentiles of the skewed TC distribution.

DB3

HEALTH CARE RESOURCE UTILIZATION AND COSTS IN INSULIN-DEPENDENT PATIENTS WITH TYPE 2 DIABETES UNDER REAL WORLD CONDITIONS IN GERMANY: LIVE-SPP STUDY

Schöffski O[1], Dippel FW[2], Breitscheidel L[3], Benter U[3], Müller M[4], Volk M[4]

[1]Universität Erlangen-Nürnberg, Nürnberg, Germany, [2]Sanofi-Aventis Germany GmbH, Berlin, Germany, [3]Kendle GmbH, Munich, Germany, [4]axaris software&systeme GmbH, Ulm, Germany

OBJECTIVES: To evaluate and compare the total costs relevant to diabetes care in patients with type 2 diabetes mellitus (T2D) treated with either Insulin glargine- or conventional basal insulin (NPH)-based therapies from the perspective of the German statutory health insurance (SHI). **METHODS:** LIVE-SPP (**L**ong acting **I**nsulin glargine **V**ersus NPH Cost **E**valuation in **SP**ecialised **P**ractices) Study is a naturalistic, retrolective, multicenter study of adult patients with T2D. Costs were evaluated from the German SHI perspective in 2005. Average total costs per patient for Insulin glargine-based vs. NPH-based therapies were compared over the 20-month period using multivariate general linear modelling (GLM). Potential confounders tested were age, gender, BMI, HbA1c, FBG, duration of diabetes, duration of insulin pre-treatment, and number of diabetic complications at baseline. Sensitivity analyses were performed by varying the main cost factors by ±25%. **RESULTS:** Patients (n = 1024, 512 patients per cohort) were on average 62 years old, with an average BMI of 30.5 kg/m^2. Average duration of diabetes history at study start was eight years with an average duration of insulin pre-treatment of seven months. The average unadjusted total costs per patient from the SHI perspective per 20-month period were €3114.02 [95% CI 2907.12–3320.93] for Insulin glargine-based vs. €3439.54 [95% CI 3204.85–3674.23] for NPH-based therapies. The major cost drivers for both cohorts were insulin utilization, physician visits and blood glucose monitoring. Average adjusted total costs per patient were statistically different between Insulin glargine-based (€2068.55) and NPH-based therapies (€2679.77), 20-month period, p = 0.0004, resulting in adjusted savings of €611.22 in favor of Insulin glargine based therapies. The economic advantage for Insulin glargine-based therapies remained stable in sensitivity analyses. **CONCLUSIONS:** LIVE-SPP cost analyses indicate that Insulin glargine-based therapies offer an economic advantage over NPH-based therapies, resulting in potential cost savings.

DB4

COST OF MANAGING SEVERE HYPOGLYCAEMIA IN INSULIN-TREATED DIABETES IN THREE EUROPEAN COUNTRIES

Hammer M[1], Lammert M[2], Frier BM[3]

[1]Novo Nordisk A/S, Bagsværd, Denmark, [2]Novo Nordisk Scandinavia AB, Copenhagen, Denmark, [3]Royal Infirmary of Edinburgh, Edinburgh, UK

OBJECTIVES: To assess the costs incurred in management and follow-up of severe hypoglycaemic events (SHEs; requiring external help for recovery) in Germany, Spain and the UK. **METHODS:** In 639 people aged ≥16 years and receiving insulin for type 1 (n = 319) or type 2 diabetes (n = 320) who experienced ≥1 SHE in the previous 12 months, health care resource use was measured for the most recent event via patient surveys. Patients were grouped by where the SHE was treated: Group 1, community (lay person); Group 2, community (health care professional, HCP); Group 3, hospital. Costs were calculated by applying unit costs from published sources to estimated resource use; costs per SHE were calculated by dividing by the number of patients per subgroup. Weighted average costs across all treatment groups were derived using prevalence data from the Roper Starch database. **RESULTS:** Hospital treatment is a major cost driver for SHEs in all countries, despite most patients being treated in the community. Costs per SHE were similar for type 1 and type 2 patients in all three countries, e.g. in Germany (Groups 1–3 respectively), €52, €482 and €3671 for type 1 diabetes and €30, €354 and €3366 for type 2 diabetes. The average cost per SHE (all patients) for Germany, Spain and UK respectively was €522, €466 and UK£164 (€242*) in type 1 patients and €595, €572 and UK£358 (€527*) in type 2 patients (*€1.00 = UK£0.679; average rate, 2/06–3/07). More patients with Type 2 than Type 1 diabetes are treated by HCPs in the UK, resulting in higher costs. Calls and visits to family doctors, additional glucose testing and education about diabetes management contribute substantially to total costs in non-hospitalised patients. **CONCLUSIONS:** SHEs add significantly to health care costs. SHE treatment costs were similar in all three countries, despite differences in management approach.

PODIUM SESSION IV: HEALTH POLICY ISSUES AND IMPLICATIONS

HP1

ANALYSIS OF THE ORPHAN DRUG DESIGNATIONS AND APPROVALS GRANTED BY THE EMEA AND THE USA FDA BETWEEN 2000 AND 2007

Seoane-Vazquez E[1], Rodriguez-Monguio R[2]

[1]The Ohio State University, Columbus, OH, USA, [2]University of Massachusetts, Amherst, MA, USA

OBJECTIVES: The United States (U.S.) Orphan Drug Act (1983) and the European Union (EU) orphan drug legislation (2000) established several incentives to encourage the development of