Abstracts

comes of adding biphasic insulin aspart 30 to metformin and pioglitazone (BIAsp30 + met + pio) compared to maintaining optimized oral therapy alone (met + pio). METHODS: Treatment efficacy, safety, and baseline demographic data of patients randomized to either therapy were derived from a recent 34-week controlled trial (n = 200; mean age 53.8 years; baseline HbA1c 8.1%; BMI 32.9 kg/m2; 42% male). Over the trial period, significant improvements in HbA1c were demonstrated for BIAsp30 + met + pio (~1.5 % between arms; p < 0.0001), though minor hypoglycaemia increased (p < 0.01). A validated and peer-reviewed economic model utilizing 2nd order Monte-Carlo simulation with tracker variables and non-parametric bootstrapping (15 interdependent Markov sub-models of diabetes-related complications) calculated life expectancy (LE), quality-adjusted life expectancy (QALE), incremental cost-effectiveness (ICER), and cumulative complication events over 35 years (base-case). Total management costs were calculated (annual pharmacy plus complication; US Medicare perspective). Clinical and cost outcomes were discounted at 3% per annum. Sensitivity analyses were performed. RESULTS: End-of-study clinical improvements demonstrated with BIAsp30 were projected to increase LE (0.66 years), QALE (0.55 quality-adjusted life years (QALYs)), and reduce cumulative incidences of diabetes-related complications, notably retinopathy, renal, and cardiovascular disease. An ICER of $22,209/QALY gained was generated, with an acceptability curve (willingness-to-pay of $50,000/QALY) portraying BIAsp30 to have a 98.4% probability of being cost-effective. Sensitivity analyses supported these results. CONCLUSION: Type 2 diabetes patients may significantly improve glycaemic control with BIAsp30 versus optimizing oral therapy alone. Through long-term health outcome projections, BIAsp30 was estimated to improve quality-adjusted life expectancy and reduce diabetes-related complications in a cost-effective manner.

THE COST-EFFECTIVENESS OF INHALED INSULIN IN SWEDEN
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OBJECTIVE: To estimate the cost-effectiveness of inhaled insulin (INH) in Type 1 (T1DM) and Type 2 diabetes mellitus (T2DM) patients uncontrolled on current treatment. METHODS: Cost-effectiveness analysis was conducted from Swedish health care perspective using the Economic Assessment of Glycemic control and Long-term Effects of diabetes (EAGLE) simulation model. EAGLE uses risk equations for the probability of micro- and macrovascular complications derived from UKPDS, WESDR and DCCT. Patient characteristics were obtained from the Swedish National Diabetes Registry. Complication costs and health-state utilities were taken from the literature. Equivalent efficacy was assumed for inhalation and standard insulin regimens. INH was assumed to result in earlier initiation or better intensification of insulin therapy. Data on intensification inertia were taken from a retrospective study and intensification differential (between INH and standard treatment) was taken from published literature. The analysis was performed over a 20y time-horizon. Costs (SEK2005) and quality-adjusted life-years (QALYs) were discounted by 3% per annum. RESULTS: Treatment costs were higher for all subgroups using INH, while the costs of complications were lower, and survival and utility higher. ICER’s for INH compared to staying uncontrolled on basal-bolus for T1DM and T2DM were SEK 38,948 and SEK 151,186/QALY, respectively. In T2DM patients uncontrolled on 2 Y2 orals ICER’s for INH compared to intensifying to basal or mix-insulin were SEK 178106 and SEK 16,2294/QALY, respectively. For patients uncontrolled on basal insulin ICER’s for INH compared to intensifying either to mix-insulin or basal-bolus were 265,376 and 232,442SEK/QALY, respectively; and in patients on mix-insulin the ICER’s for INH compared to intensifying to basal-bolus were 183,132SEK/QALY. Results were robust to changes in discount rate and intensification differential, although more sensitive to the level of treatment-associated utilities. CONCLUSION: For T1DM and T2DM patients uncontrolled on current treatment, a regimen including INH appears to be cost-effective when taking long-term micro- and macrovascular outcomes into account.

COST OF A MAJOR HYPOGLYCAEMIC EVENT IN TYPE 1 AND TYPE 2 DIABETIC PATIENTS—A SYSTEMATIC LITERATURE REVIEW
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OBJECTIVES: The largest proportion of costs in diabetes is due to complications of the disease. Hypoglycaemia is a common, chronic complication of drug treatment in diabetes. The aim of this study was to survey the cost of a major hypoglycaemic event. METHODS: A systematic literature review was carried out on all relevant assessments found in published literature. A study was regarded relevant if it included the cost of a major hypoglycaemic event. RESULTS: Relevant studies were found in the following countries: Canada, Germany, Sweden, Switzerland, UK and US. Five studies collected primary data and six studies based the cost of a hypoglycaemic event on assumptions around treatment patterns. A major hypoglycaemic event was defined differently in the different studies. Four studies defined the state as requiring third-party medical intervention which means assistance from health care services with costs ranging from £293 to £586. The state was also defined as requiring third party assistance by medical and/or family assistance in four studies, these estimates ranged from £190 to £1643. One study defined the state as requiring assistance from another person excluding medical intervention (659), while two studies defined the state from the ICD-9-CM codes, which requires a visit to a healthcare provider and presented costs at £950 and £4083, respectively. The difference in costs between the studies can be explained by different health care systems, whether direct and/or indirect costs were included and whether hospitalisation was excluded. Indirect costs were included in three studies. CONCLUSIONS: Which costs to include in a study is determined by which definition of a major hypoglycaemic event that is chosen. For this reason it is important that health economic models apply matched definitions to the clinical studies they are modelling.

COST OF INPATIENT AND OUTPATIENT CARE OF SWEDISH PATIENTS WITH DIABETES MELLITUS
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OBJECTIVES: The present analysis estimated overall annual inpatient and outpatient costs incurred by Swedish patients with diabetes mellitus between 2000 and 2004 based on data from the RECAP study, which included medical records on 13,873 patients with diabetes mellitus retrospectively identified in computerised registers at 26 primary care centres in Uppsala county. Patients included in the study fulfilled at least one of the fol-
lowing three criteria: 1) diagnosis of diabetes mellitus; 2) prescription of oral anti-diabetic drug; and 3) fasting blood or plasma glucose value indicative of diabetes. The average length of follow-up upon inclusion was 4.5 years. METHODS: Costs of inpatient care were estimated by classifying hospitalisations of study patients into diagnosis-related groups (DRGs) according to the Nord-DRG classification system and assigning average costs per DRG (2002 prices) according to a national list relying on individual patient level costs incurred at Swedish hospitals applying the Nord-DRG system. Costs of outpatient care were estimated by assigning unit costs of outpatient care-giver contacts obtained from published sources to data on study patients’ care-giver contacts as recorded in medical records at participating primary care centres. RESULTS: The average annual cost of inpatient care over the studied years was €1088 per patient (SD €4460; n = 9292 on average). Between 2000 and 2004, an annual increase in costs of between 9% and 15% was observed (constant prices). The average annual cost of outpatient care during the studied years was €363 per patient (SD €347) with little variation over the years. GP visits accounted for 40% of outpatient costs, the average patient making 1.7 GP visits per year. CONCLUSIONS: Diabetes continues to impose a heavy economic burden on society. Cost estimates from this population-based sample of Swedish diabetic patients may serve as reference values for a Swedish setting.

**PDB26**

**COST-EFFECTIVENESS OF ROSIGLITAZONE FOR TREATMENT OF TYPE 2 DIABETES IN PORTUGAL USING DIFFERENT METHODS TO MODEL CLINICAL EFFECTS**

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OBJECTIVES: The result study demonstrated that sulphonylurea (SU) plus rosiglitazone (RSG) provided a sustained and substantial increase in beta-cell function (BCF) from baseline (56%, p < 0.0001) compared to SU alone (6%, p = 0.41). This modelling study explores the impact on disease progression, health outcomes and health care expenditure in Portugal of different approaches to modelling RSG’s effect on BCF. METHODS: DiDiACT, a peer-reviewed published long-term model of T2DM, was used to replicate patient characteristics (73% male, mean age 68.2 years, mean BMI 30 kg/m2) and the impact of SU + RSG on BCF observed in the recent study using an additive, a multiplicative or combined approach. Disease progression for 1000 hypothetical patients, projected total lifetime health care costs and health gains, measured in time to insulin and quality-adjusted life years (QALYs) was predicted. Following failure of intermediate SU dose to maintain glycaemic target, up-titrated SU therapy was compared to SU + RSG combination. The treatment change threshold was HbA1c ≥ 7.5%. Resources were valued using national unit costs from a variety of sources. Costs and outcomes were discounted at 5% per year. RESULTS: Both revised calibrations yielded lower lifetime health care costs and additional QALYs, compared to the original calibration. Compared with SU alone both revised calibrations resulted in reduced costs, increased QALYs and time to insulin when compared with the original calibration. The use of RSG in the management of T2DM appears to be cost-effective in all scenarios investigated. Forthcoming long-term studies of RSG may confirm the impact of RSG on BCF observed and enable determination of the most appropriate method for model calibration.

**PDB27**

**A COST-UTILITY ANALYSIS OF ORLISTAT (XENICAL®) IN THE TREATMENT OF DIABETIC PATIENTS WITH MORBID OBESITY AND ADDITIONAL CVD RISK IN NORWAY**

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OBJECTIVES: The co-epidemics of obesity and type II diabetes and associated complications result in an increasing population with high risk of serious morbidity, mortality and reduced quality of life. This analysis has been specifically developed to estimate the cost and quality adjusted life year (QALY) gained with orlistat compared to standard clinical practice (SCP) in a particularly high-risk diabetic population with morbid obesity (BMI ≥ 35 kg/m2 and at least one additional CVD risk). In Norway this is a population with clearly unmet needs for preventive medical interventions. METHODS: The incremental cost-utility is calculated in an Excel-model comparing 1 year of orlistat treatment followed by 9 years of SCP with 10 years of SCP. The baseline risk is based on the findings of the UK Preventive Diabetes Study (UKPDS), adjusted for differences in BMI. The effects of orlistat and SCP (conservatively assumed to placebo + SCP) on risk factors (BMI, HbA1c, LDL-cholesterol, SBP), are based on results from the relevant randomized clinical trials. 3 years catch-up of risks after termination of orlistat is assumed. UKPDS and the Heart Protection Study provide assessments of the change in risk associated with change in HbA1c and the other relevant risk factors. Effects on utility are based on the results from CODE-2. Direct costs related to the treatment alternatives and their associated complications are included from a Norwegian societal perspective. RESULTS: The expected incremental cost of treating high-risk Norwegian diabetic morbid obese patients with orlistat is approximately €312.5/QALY. Extensive one- and multiway sensitivity analyses using Monte Carlo simulation indicate robustness of the results. CONCLUSIONS: The results of this model indicate that one year treatment with orlistat is a highly cost-effective alternative to SCP for diabetic patients with morbid obesity and additional CVD risk in Norway.

**PDB28**

**INADEQUATE GLYCEMIC CONTROL: IS IT RELATED WITH MORE COMORBIDITIES AND MORE RESOURCE UTILIZATION?**

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OBJECTIVE: To evaluate the influence of inadequate glycemis control (IC) in comorbidity and health resource utilization of type 2 diabetic patients treated in a general practitioner setting. METHODS: Retrospective observational study (systematic-sampling) of patients older than 18 years, treated in 5 primary care centres during 2005. The following parameters were evaluated: IC, defined by HbA1c > 7%; age, sex; comorbidities (hypertension, hypercholesterolemia, smoking, obesity, ischemic-heart-disease, cardiovascular event (CVE), COPD, depression, cardiac-renal-hepatic insufficiency, microvascular complications); clinical parameters (BMI, total-cholesterol, LDL-Friede-