tically significant for both feet (p<0.001). Hyperkeratosis of both feet, evaluated by the doctor, significantly improves after 4 weeks of treatment. The efficacy score measured by the patient is 16.4 (± 4.8) on inclusion. Measured under the same conditions, it is 7.7 (± 3.2) at 4 weeks. The difference is statistically significant (p<0.001). Treatment compliance is good since 89% confirm that they respected the dosage, a trend confirmed by the fact that 94% of subjects say that they are satisfied with the product. **CONCLUSIONS:** By means of a validated score (XAS) and a patient evaluation scale, the efficacy of Pedimed in treating the diabetic foot is confirmed.

PDB19

PREVALENCE OF DIABETES MELLITUS AMONG PATIENTS WITH VASCULAR COMPLICATIONS IN POLAND

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OBJECTIVES: The objective of this study was to estimate a prevalence of diabetes mellitus (DM) among patients with micro- and macrovascular complications in Poland, like angina pectoris, myocardial infarction (MI), stroke, lower limb ischemia, end-stage renal disease (ESRD), and their consequences like heart failure, visual disorders or amputations. **METHODS:** The estimation was based on observational studies, which were identified by searching medical databases and Polish registries. Publications were selected in a specific order, to ensure that included data are the most representative for Polish population. Firstly, studies conducted in Polish settings were included and, if no reliable publications were found, European, non-European Caucasian and other (not specified) population were analyzed. Population based registries were considered as the most appropriate type of data. When no registry was available systematic reviews of observational studies were included. If systematic review was not available – data from clinical studies were taken into account. **RESULTS:** According to polish registries, DM was present in 28% of patients with non-ST-elevation MI, 20% of patients with ST-elevation MI, 22% of patients with unstable angina and 22% patients with ESRD. The results of two studies regarding Polish population indicate that 15.3% of patients with stable angina pectoris suffer from DM. The results of studies coming from European countries identified by literature search showed that DM was diagnosed in 26.2% of patients with heart failure, 21.5% of patients with stoke, 40% of patients hospitalized for peripheral artery disease, 52.8% of patients with lower-extremity amputation and 67.1% of patients with non-traumatic amputations. Diabetes was present in 34.9%, 9.4% and 7.1% of patients with retinopathy, vision disorders and blindness respectively. **CONCLUSIONS:** DM often co-exists with vascular disorders in Poland. It affects 15% of patients with macrovascular complications and more than 20% of patients with microvascular complications.

PDB20

A1C VARIABILITY AND THE RISK OF DEVELOPING NEW DIABETES FOR THE HEALTHY ADULTS IN JAPAN

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OBJECTIVES: To evaluate the effect of A1C variability on the risk of developing new diabetes in healthy adults in Japan. **METHODS:** Population-based, retrospective cohort from 2005 to 2008 in Tokyo, Japan. In healthy adults not taking diabetes medication and with lower than 6.5 of HbA1c at baseline, we measured annually the serum HbA1c and calculated the annual visit-to-visit variability. **RESULTS:** At baseline, 14,764 people (49% female) with a mean age of 50 years old (SD: 12 years, range: 23 to 92), a mean fasting plasma glucose (FPG) level of 98.4 mg/dl (SD: 9.3 mg/dl) and a mean HbA1c level of 5.3 % (SD: 0.4 %) had annual check-ups over 4 years. Using the multivariate logistic regression, the A1C variability (odds ratio (OR): 7.8 for highest quantile interval (>= 0.16%)) versus the lowers quantile (<0.08 %), 95%CI: 4.8 – 12.8) and the baseline A1C (OR: 43.3 for group with 6.0 – 6.4 % of A1C versus with <5.0 %, 95% CI: 10.4 – 181.4) were independently predictive of new diabetes after adjusting for the other potential risk factors. FPG (OR: 1.1, 95%CI: 1.1 – 1.2) and Smoker (OR: 1.6, 95%CO: 1.2 – 2.3) also significantly related to develop the new diabetes. **CONCLUSIONS:** Visit-to-visit variability in A1C independently added to the baseline A1C in predicting the risk of developing new diabetes for the healthy adults.

PDB21

NATURAL HISTORY OF BETA CELL RATE OF DECLINE AND ITS EFFECT ON DEVELOPMENT OF SECONDARY COMPLICATIONS IN TYPE 1 DIABETES

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OBJECTIVES: Beta cells in the pancreas are responsible for secreting insulin in response to increases in blood glucose. Proinsulin C-peptide (C-peptide), co-secreted with insulin, is a marker for beta cell function. C-peptide levels at type 1 diabetes (T1D) diagnosis and rate of decline (ROD) post diagnosis are important when evaluating the potential beta cell-preserving therapies to maintain better glycemic control and reduce complications. Because little is known about factors that affect C-peptide levels at diagnosis and ROD, we aimed to summarize known factors. **METHODS:** We conducted a systematic review of literature in PubMed (English only) from 1987 using the following key words alone and in combination: type 1 diabetes, c-peptide, rate of decline, concentration, epidemiology, residual beta cell function, diagnosis. Additionally articles were identified from the reference lists of selected journal articles. **RESULTS:** The review indicated that: 1) Decline of beta-cell function begins years before T1D diagnosis; 2) At diagnosis stimulated C-peptide concentrations range from 0.32±0.26 pmol/mL (mean±SD) to 1.4±0.8 pmol/mL (mean±SD); 3) Stimulated C-peptide ROD can range from -0.00 to -0.01 pmol/mL/month; 4) Lower C-peptide concentrations at diagnosis are partly explained by younger onset age, time since diagnosis, genetic factors and a high-titer presence of islet cell autoantibodies; and 5) Intensive therapy to treat T1D of ≥3 insulin injections daily reduces the C-peptide level after 1 year by 0.21±0.03 pmol/mL versus 0.15±0.02 pmol/mL for less intensive treatment of 1-2 injections. **CONCLUSIONS:** Understanding the factors that influence C-peptide ROD may help researchers develop strategies which address heterogeneity of response to therapy, resulting in improved glycemic control and reduction in complications such as ketoacidosis, neuropathy or nephropathy. Including parameters for C-peptide and its ROD in pharmacoeconomic models may help estimate the burden of these complications in T1D, and help quantify the benefits of preserving beta cells.

PDB22

'REAL-WORLD' CLINICAL OUTCOMES OF EXENATIDE BID COMPARED TO INSULIN GLARGINE IN PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: The safety and efficacy of exenatide BID (exenatide) compared to insulin glargine (glargine) has been studied in clinical trials and use of exenatide has been associated with reductions in A1C and weight. This study examined the clinical outcomes of exenatide versus glargine in patients with type 2 diabetes in a 'real-world' ambulatory care setting. **METHODS:** A retrospective analysis was conducted using the General Electric electronic medical record database to select exenatide (n=4,494) and glargine (n=5,424) cohorts. These cohorts were propensity-score matched to control for baseline demographic, clinical, and resource use variables (2,683 matched pairs). Matched cohorts were compared using paired t-tests and nonparametric tests as appropriate. The effectiveness endpoints were changes in A1C (primary endpoint), weight, body mass index (BMI), blood pressure (BP), lipid levels, and hypoglycemia rates. **RESULTS:** The matched exenatide and glargine cohorts had comparable age (58 vs. 58 years), females (55% vs. 53%), and baseline clinical characteristics. In a 12-month follow-up period, the exenatide cohort achieved greater mean (±SD) reduction in A1C (-0.66% [±1.5] versus -0.41% [±1.7], P<0.01), weight (-2.6 [±6.8] vs. -0.2 [±9.2] kg, P<0.01), BMI (-0.9 [±2.6] versus -0.1 [±2.7] kg/m^2, P<0.01), and systolic BP (-1.8 [±17] vs. -0.3 [±18] mmHg, P<0.01). More exenatide-treated patients reached the A1C goal of <7% (46% vs. 36%, P<0.01). There were no clinically significant differences in diastolic BP, lipid levels, and hypoglycemia rates between cohorts. **CONCLUSIONS:** Exenatide-treated patients experienced significantly greater reductions in A1C, weight, BMI, and systolic BP than the glargine cohort. These results demonstrated the clinical effectiveness of exenatide compared to glargine in a large, diverse, 'real-world' patient population treated in the ambulatory care setting.

Diabetes/Endocrine Disorders – Cost Studies

PDB23

BUDGET IMPACT ANALYSIS OF THE REIMBURSEMENT OF LONG-ACTING INSULIN ANALOGUES IN POLAND

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OBJECTIVES: According to HTA reports regarding long-acting insulin analogues (LAIA) these drugs should be reserved for use in selected diabetic patients only. In line with recent knowledge LAIA in Poland are planned to be reimbursed in framework of therapeutic programme (LAIA-TP). This study assess the impact of this decision on public health-payers budget. **METHODS:** The analysis was perfomed using modelling technique, based on systematic review of LAIA, Polish epidemiologic and costing data. Two scenarios were compared: (A) LAIA not reimbursed, (B) LAIA reimbursed for patients with episodes of severe hypoglicaemia (after 6 months reimbursement continued only in patients successfully treated). In each scenario annual costs of insulinotherapy, monitoring and tretament of hypoglicaemia were estimated in 3-years time horizon. Model was run by having the current patient cohort progress through the model accompanied by the addition each year of a new cohort of eligible patients. Extreme scenario sensitivity analyses were performed. **RESULTS:** The expected number of diabetic patients eligible for LAIA would be 12,611 in the 1st year, and each year 661 "new" patients will meet inclusion criteria. Only 25% patients with type 1 and 30% patients with type 2 diabetes will be successfully treated with LAIA. The introduction of LAIA-TP is expected to increase public-payers expenditure in years 1st -3th by 12,168,582, 7,972,737 and 8,321,552 PLN, respectively (1 PLN=0.25 EURO, 2011). Such an increase in cost would be associated with acquisition cost of LAIA and would be only partially compensated by lower costs of monitoring and treatment of hypoglicaemia. Depending on assumptions about population and effectiveness of LAIA the additional expenditures of public payer varies between 11,295,941- 8,962,648 PLN, 7,219,765-9,627,449 PLN and 7,556,552-10,505,485 PLN in 1st, 2nd and 3rd year, respectively. **CONCLUSIONS:** Budget impact analysis indicates that reimbursement of LAIA-TP seems to be affordable to the budget holder.

PDB24

BUDGET IMPACT ANALYSIS OF THE USE OF ASPART INSULIN DURING HOSPITALIZATION OF PATIENTS WITH HYPERGLYCAEMIA IN ITALY

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OBJECTIVES: Hyperglycaemia is a frequent condition in hospitalizations for acute conditions, not always correlated with a previous presence of diabetes. Patients with hyperglycaemia experiment a worse prognosis, with increased mortality, complications and a longer hospital stay than normal ones. Several evidences in

literature demonstrate that the outcome can also be influenced by the insulin regimen used by the hospital. Objective of this study is the Budget Impact Analysis (BIA) of the hospital use of aspart insulin with respect to other rapid insulin alternatives available on the market. **METHODS:** All the hospitalizations with evidence of hyperglycaemia in one year in Italy were considered. Four alternatives were evaluated: 1) aspart insulin; 2) lispro insulin; 3) glulisine insulin; 4) human insulin. Administration of insulin regimen (basal + rapid), length of hospital stay and incidence of hypoglycaemic events were simulated. The rates of hypoglycaemic events with rapid insulin alternatives, and the prolongation of hospital stay caused by such an event were derived from international literature. Only differential costs among alternatives were accounted for, i.e. purchase and administration of rapid insulin and management of hypoglycaemic events. Epidemiologic and healthcare resource consumption data derived from Italian published sources. Current prices and tariffs were applied in the perspective of the hospital. **RESULTS:** A total of 7.7 million hospitalizations of adult patients in one year were considered, of which 23.6% (1.8 million) with evidence of hyperglycaemia. Total costs with the aspart insulin resulted: €7.8 million for insulin, €7.4 million for administration and €507.0 million for hypoglycaemic events management (total: €522.2 million). Total costs with the other rapid insulin alternatives were higher (range: +4% to +37.2%). **CONCLUSIONS:** Aspart insulin has a listed purchasing cost in Italy equal or higher than alternatives, but the BIA indicates that its adoption can yield savings for the hospital, being the hypoglycaemic events management the main cost driver.

PDB25

REAL-WORLD OUTCOMES OF INITIATING TWO DIFFERENT BASAL INSULIN THERAPIES VIA DISPOSABLE PENS AMONG PATIENTS WITH TYPE 2 DIABETES IN US EMPLOYER-SPONSORED HEALTH PLANS

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OBJECTIVES: Among patients with type-2 diabetes mellitus (T2DM) previously treated with only OADs, to evaluate real-world differences in clinical and economic outcomes following initiating basal analog insulin therapy via disposable pen with either glargine (GLA-P) or detemir (DET-P). **METHODS:** The MarketScan databases (2006–2010) were used to identify patients with T2DM aged 18–79 years and receiving ≥1 OAD, but no insulin before initiation of GLA-P or DET-P. Patients had continuous health plan enrollment for 6 months prior to (baseline) and 1 year after GLA-P or DET-P initiation (follow-up). Propensity score matching 1:1 was applied to match the two patient cohorts using baseline demographic and clinical factors. Study outcomes included treatment persistence and adherence, hypoglycemia-related medical events, and healthcare utilization and costs during the follow-up. **RESULTS:** The 2 matched cohorts (n=5771 each, mean age 54, female 49%) were well balanced for baseline characteristics (all $P>0.1$). During follow-up, patients initiating GLA-P were more likely to be persistent (42.9 vs. 38.4%, $P<0.001$) and adherent (adjusted medication possession ratio 0.70 vs. 0.67, $P<0.001$) with treatment versus those initiating DET-P. The average daily study drug consumption dose was 33U in both cohorts. Fewer GLA-P than DET-P users returned to OAD-only (18.6 vs. 20.5%, $P=0.011$). Hypoglycemia-related medical events were similar (0.7 vs. 1.0%, $P=0.093$), while the mean number of hypoglycemia-related emergency room (ER) or hospital events per patient was lower for GLA-P (0.006 vs. 0.012, $P=0.010$). The diabetes-related pharmacy costs were similar for GLA-P and DET-P ($2,465 vs. $2513, $P=0.155$), as were the total health care costs ($16,058 vs. $16,209, $P=0.69$). **CONCLUSIONS:** Real-world T2DM patients initiating insulin therapy via disposable pen with GLA-P were more likely to persist and adhere with treatment compared with patients initiating with DET-P. GLA-P users had fewer ER-/hospital-related hypoglycemia events, while costs were similar for both.

PDB26

PROJECTED LONG-TERM CLINICAL AND ECONOMIC OUTCOMES OF EXENATIDE ONCE WEEKLY VERSUS SITAGLIPTIN FOR THE TREATMENT OF TYPE 2 DIABETES IN THE UK

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OBJECTIVES: The aim of this analysis was to estimate the long-term incremental clinical and cost outcomes associated with exenatide once weekly (EQW) versus sitagliptin therapy in type 2 diabetes patients in the UK. Data from DURATION-2; a phase 3, multinational, randomised, double-blind clinical trial in 491 patients with type 2 diabetes previously treated with metformin were used. After 26 weeks, patients receiving EQW (n=160) had a significantly greater LS mean HbA1c reduction (-1.6% versus -0.9%, respectively) and weight reduction (-2.3 kg versus -0.8 kg, respectively) than patients who received sitagliptin (n=166). **METHODS:** A previously published and validated diabetes model (IMS CORE Diabetes Model) was used to make 50 year projections of clinical and cost outcomes based on DURATION-2 baseline patient characteristics and study results. Costs were derived from published sources and expressed in 2010 UK Pounds. A discount rate of 3.5 % was applied to both costs and outcomes. Various sensitivity analyses were performed. **RESULTS:** EQW treatment was projected to improve quality-adjusted life expectancy by 0.22 quality-adjusted life years (QALYs) (95% confidence interval 0.12 to 0.32) versus sitagliptin. Total direct medical costs associated with EQW were projected to be higher over patient lifetimes than with sitagliptin (difference of £1405, 95% confidence interval £444 to £1982), due to higher drug acquisition costs, which were partially offset by the lower incidence of diabetes-related complications during treatment with EQW, and hence cost of treating. The projected incremental cost effectiveness ratio (ICER) was £6418 per QALY gained. Results of the sensitivity analysis showed that the ICER was influenced by a reduction in time horizon, decrease in EQW benefits on HbA1c and increased time on EQW. **CONCLUSIONS:** Projected from the DURATION-2 trial, EQW can be considered cost-effective versus sitagliptin in the UK setting from the NHS perspective. The results were robust to sensitivity analyses.

PDB27

PROJECTED COST-EFFECTIVENESS OF EXENATIDE ONCE WEEKLY VERSUS EXENATIDE BID FOR THE TREATMENT OF TYPE 2 DIABETES IN THE UK

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OBJECTIVES: The aim of this analysis was to estimate the cost-effectiveness of exenatide once weekly (EQW) versus exenatide BID therapy, two formulations of the same glucagon-like peptide-1 receptor agonist molecule, in type 2 diabetes patients in the UK. Pooled data from DURATION-1 and DURATION-5, phase 3, randomised, open label clinical trials in 295 and 252 patients respectively, were used. EQW was associated with greater LS mean HbA1c reduction (-1.7% versus -1.2%, respectively, p<0.001) and weight reduction (-2.9 kg versus -2.4 kg, respectively, p=0.126). **METHODS:** A previously published and validated diabetes model (IMS CORE Diabetes Model) was used to make 50 year projections of clinical and cost outcomes based on pooled DURATION-1 and 5 baseline patient characteristics (age 55.3 years, duration of diabetes 7 years, HbA1c 8.36%) and study results. Costs were derived from published sources and expressed in 2010 UK Pounds. A discount rate of 3.5 % was applied to both costs and outcomes. Various sensitivity analyses were performed. **RESULTS:** EQW treatment was projected to improve quality-adjusted life expectancy by 0.18 quality-adjusted life years (QALYs) (95% confidence interval 0.10 to 0.25) and life expectancy by 0.16 years (95% confidence interval 0.07 to 0.26) versus exenatide BID. EQW was associated with delayed onset of any diabetes-related complication versus exenatide BID by almost 6 months on average. Due to the lower incidence of diabetes-related complications during treatment with EQW, and hence reduction in their treatment costs, EQW was associated with direct medical cost savings (difference of -£305, 95% confidence interval -£715 to £35). EQW was therefore projected to be dominant versus exenatide. This result was robust to all sensitivity analysis. **CONCLUSIONS:** Based on DURATION-1 and 5, EQW was projected to be less costly and more effective than exenatide BID over a patients' lifetime in the UK setting.

PDB28

THE ROLEOF DIABETES AND BODY MASS INDEX ON MEDICAL EXPENSES, AN ANALYSIS OF THE MEDICAL EXPENDITURE PANEL SURVEY, 2008

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OBJECTIVES: The World Health Organization has recognized diabetes and other selected chronic health conditions are at an epidemic level all of which can be impacted by weight. The purpose of this project was to evaluate the role of diabetes and Body Mass Index (BMI) on total medical expenses. **METHODS:** The Medical Expenditure Panel Survey (MEPS) is publically available database providing nationally representative estimates of health care use, expenditures, sources of payment, and health insurance coverage for the US population. Analysis of the survey data utilized design-based methods that utilized the complex survey stratification and weighting. Regression was utilized to determine the effect of diabetes and BMI class on total medical expenses in 2008, with inclusion of age, gender, race/ethnicity, and insurance status as additional covariates. Models with and without two-way interactions were performed. Summary statistics are presented as mean ± standard error. **RESULTS:** All adults (≥18 years; n=22,128) were included, and average 2008 medical expenses were estimated at $4493 ± 105. All variables in the model were significant (p<0.001), and adjusting for these factors, patients with diabetes had an average medical expense of $4,512 ± 410 higher than those without diabetes. Across both cohorts, the morbid obese (BMI ≥ 40) had significantly higher covariate adjusted medical expenses than normal (18.5≤ BMI<25; +$1340 ± 414; p=0.001) and overweight (25≤ BMI<30; +$1517 ± 420; p<0.001) individuals, whereas differences with obese (30≤ BMI<40; +$784 ± 439; p=0.08) and underweight (BMI<18.5; -$88 ± 754; p=0.91) were not significant. **CONCLUSIONS:** Both diabetes and high BMI are independently associated with significantly higher medical expenses, and appear to be generally an additive effect. Increase in BMI was associated with significantly higher medical costs even without diabetes. Morbidly obese patients with diabetes had annual expenses averaging $12,004.

PDB29

MODELING THE IMPACT OF ENHANCED TREATMENT OF TYPE 2 DIABETES MELLITUS IN BULGARIA

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OBJECTIVES: To model and evaluate consequences of enhanced treatment of type 2 diabetes mellitus on cost, life expectancy and development of complications in the Bulgarian health care system. **METHODS:** The extensively published and validated CORE Diabetes Model was used to perform lifetime simulations for the representative diabetic patient in Bulgaria diagnosed at 55 years. The analysis compared two alternative treatment scenarios with current standards of care. In the first alternative scenario the model examined the human and economic costs of 10% reduction in the risk factors for developing diabetes related complications. In the second scenario consequences of treating to targets set in American Diabetes