OBJECTIVES: A recent randomized trial demonstrated that twice daily biphasic insulin aspart 30/70 (BIAsp30/70) led to significantly (p = 0.0057) better glycaemic control compared to bedtime insulin glargine in insulin-naïve type-2 diabetes patients on oral antidiabetics (HbA1c reduced by –2.79% vs. –2.36% from baseline). Patients gained more weight with BIAsp30/70 than with glargine (5.4 vs. 3.5 kg, p = 0.0013), but weight gain per unit insulin was similar. The CORE Diabetes Model, a peer-reviewed, validated, model was used to project the long term cost effectiveness of BIAsp30/70 versus glargine. **METHODS:** The CORE Diabetes model employs standard Markov/Monte Carlo simulation techniques to describe the long-term incidence and progression of diabetes-related complications. Transition probabilities were derived from major diabetes studies. Clinical effects of comparators were derived from the INITIATE study. The analysis was performed using published country-specific costs, health care resource utilization and clinical data, and recommended discount rates. A lifetime horizon and payers' perspective was taken. Only direct costs were considered. Sensitivity analyses were performed. **RESULTS:** Discounted quality-adjusted life years (QALY) were improved by 0.13–0.25 years with BIAsp30/70 versus glargine depending on country-specific discount rates. Lifetime cost savings were observed with BIAsp30/70 in the Danish, Dutch, Finnish, French, Norwegian, Spanish, and Swedish settings. Overall costs were increased with BIAsp30/70 versus glargine in the German and UK settings, with incremental cost-effectiveness ratios of 3692€ and ≤1541/QALY gained respectively. Results were most sensitive to changes in baseline HbA1c and to the relative costs of BIAsp30/70 versus glargine. **CONCLUSIONS:** Improvements in glycemic control outweighed the greater increase in body weight, leading to improved quality-adjusted life expectancy with BIAsp30/70 versus glargine. BIAsp30/70 was projected to lead to overall cost savings or would be considered cost-effective versus glargine, with costs/QALY falling well below commonly accepted international thresholds.

WILL IRBESARTAN LEAD TO COST SAVINGS DUE TO DELAYED END STAGE RENAL DISEASE IN HYPERTENSIVE TYPE-2 DIABETICS IN GERMANY?

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OBJECTIVES: Type-2 diabetes is a major health problem. 30% of all patients being on dialysis suffer from a diabetic Endstage Renal Disease (ESRD). The Angiotensin-2-Receptor-Blocker (ARB) Irbesartan has proven its capability to prevent or delay an ESRD. Based on the results of the multicentre double-blind, randomized, placebo-controlled Irbesartan Diabetic Nephropathy Trial (IDNT) the presented study aims to show that a treatment of renal diseases in hypertensive type-2 diabetics with the ARB Irbesartan is cost saving for the German health care system. **METHODS:** A cost-effectiveness analysis from the German payers' perspective was conducted taking direct costs into account. 1715 type-2 diabetics with hypertension and limited renal function were included in IDNT (2.6 years, subgroup with 300 mg/d Irbesartan). The patient number needed to treat (NNT) to prevent one ESRD was the efficacy parameter for this analysis. Public sources were used for cost data and information on dialysis and transplantation in diabetics with ESRD. Actual drug prices were used taking into account discounts and co-payments effective in Germany due to new legislation since January 2004. Due to conservative calculation no discounting was performed, follow-up treatment costs were not included. **RESULTS:** The NNT for the primary endpoint ESRD calculated to 28 during the study period of 2.6 years in IDNT. That means additional treatment costs of €25,007.—lead to one prevented ESRD (incremental cost-effectiveness-ratio). The prevented ESRD (82% dialysis, 18% transplantation) is worth €45,766.—which shows a benefit for Irbesartan treatment of €20,758.—after 2.6 years or €7984.—per year assuming a linear trend towards delay in ESRD. A sensitivity analysis stated the robustness of the data. **CONCLUSIONS:** Based on epidemiologic data our results suggest savings for the German health care system of €3.2 billion after 2.6 years if annually additional €681 million were invested in the treatment of type-2 diabetics with Irbesartan.

THE VALUE OF ORAL MONOTHERAPY ALTERNATIVES IN THE FIRST-LINE TREATMENT OF TYPE-2 DIABETES MELLITUS

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OBJECTIVES: To construct a lifetime model evaluating potential health benefits and costs applying to Scottish Type-2 diabetes mellitus patients initiating first-line oral monotherapy, for whom metformin is inappropriate because of contra-indications or intolerance. When lifestyle modification (diet and exercise) affords inadequate glycaemic control, these patients currently have no alternative to sulphonylurea (SU) therapy. The model compared novel agent pioglitazone (PIO) versus generic SU treatment. **METHODS:** A decision-analytic Markov model was constructed using published (UKPDS) cost data for diabetes management and co-morbidity treatment. Three prospective treatment pathways were explored: first-line PIO/second-line PIO + SU combination/third-line insulin; first-line SU/second-line PIO + SU combination/third-line insulin; and first-line SU/second-line insulin. The model incorporated efficacy evidence of glycaemic control under PIO and SU, measured as initial HbA1c improvements and the rate of disease progression in terms of HbA1c (the coefficient of failure). **RESULTS:** Patients treated with PIO achieved better HbA1c control and improved serum lipid profiles, which translated into fewer diabetic complications, better quality of life and improved overall survival. Additional drug costs of PIO over SU were partly offset by lower costs to treat and manage diabetes complications, and delayed insulin therapy. The estimated incremental cost per QALY gained of PIO was £2415 compared to SU (when followed by second-line PIO/SU and third-line insulin therapy). The incremental cost per QALY gained of PIO was £1514 compared to SU (when followed by second-line insulin therapy). **CONCLUSIONS:** Clinical trial evidence indicated superior glycaemic (HbA1c) control in patients treated with PIO, in comparison with those treated with SU. The model showed that PIO is a cost-effective intervention and thus a valuable addition to first-line treatment options for patients intolerant and/or contra-indicated to metformin. Importantly, initiating PIO as second-line combination treatment after first-line SU in this patient group was less efficient than providing PIO monotherapy in a first-line setting.

THE COST-EFFECTIVENESS OF PIOGLITAZONE IN COMBINATION WITH METFORMIN IN THE TREATMENT OF TYPE 2 DIABETES MELLITUS IN SCOTLAND

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OBJECTIVES: To develop a lifetime model of Type-2 diabetes mellitus and its sequelae, to compare the costs and benefits of

pioglitazone plus metformin (PIO + MET) versus sulphonylurea plus metformin (SU + MET) oral combination therapies in patients with insufficient glycaemic control despite maximal tolerated dose of metformin monotherapy. **METHODS:** A decision-analytic model employing a Markov process was constructed using TreeAge DATA. The model incorporated efficacy evidence from a key clinical trial comparing the glycaemic control of PIO + MET versus SU + MET, as measured by initial improvements in HbA1c and the rate of disease progression in terms of HbA1c (the coefficient of failure). Treatment pathways reflecting best practice in Scotland, including third-line insulin therapy, were modelled, with published (UKPDS) cost data of diabetes management and co-morbidity treatment. **RESULTS:** Patients treated with PIO + MET achieved better HbA1c control and improved serum lipid profiles, which translated into fewer diabetic complications, better quality of life and improved overall survival. Additional drug costs of PIO + MET over SU + MET were partly offset by lower costs to treat and manage diabetes complications, and delayed third-line insulin therapy. PIO + MET patients incurred mean additional costs of £1217 per patient and gained 0.05 additional quality-adjusted life years (QALY's) per patient compared to SU + MET patients. The estimated incremental cost per QALY gained of PIO + MET compared to SU + MET was £25,599. If a QALY is valued at £30,000, PIO + MET is associated with a net health benefit of £209 per patient (95% confidence interval: −£6679 to £8076). **CONCLUSIONS:** The relationship between HbA1c and the incidence of complications in Type-2 diabetes is well established. Evidence from a large head-to-head trial indicates superior glycaemic (HbA1c) control accompanied by significantly improved serum lipid profiles in patients treated with PIO + MET. Given that PIO + MET provides a positive net health benefit, therefore PIO + MET is a cost-effective intervention relative to current treatment in Type-2 diabetes.

PDB11

PHARMACOECONOMIC ASPECTS OF USE OF INSULIN GLARGINE IN TREATMENT OF DIABETES MELLITUS TYPE 2 (DM T2) IN RUSSIA

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OBJECTIVES: To conduct a prognostic evaluation of the total cost of treatment of DM T2 and its complications, to estimate the economic effectiveness of the use of insulin glargine. **METHODS:** At stage 1, the costs of treatment of 500 patients in DM T2 from 15 regions of Russia were studied. At stage 2, the predicted prevalence of complications over 10-year time interval and their cost was calculated by the Diabetes Mellitus Model (DMM) using. At stage 3, the total cost of treatment of DM T2 patients in Russia based on the State Register of Diabetes Patients at the moment of the study and prospectively at the 10th year from the start was calculated. The method of cash flow discounting according to the formula $á = 1/(1 + ri)i$ was used, where $á$ is the discounting coefficient, i is the consecutive number of the period, and ri is the discounting rate in the i-th period in fractions of a unit. **RESULTS:** According to data of previous comparative studies, the use of insulin glargine leads to reach a lower level of HbA1c versus NPH insulins, and this difference amounts to 0.85%. Taking into account these data, decreases in the predicted prevalence at the end of the 10-year period pro-vided that insulin glargine was used, in comparison to NPH insulin, would amount to 18% for mi-crovascular complications, 25% for chronic renal insufficiency, 10% for macrovascular complica-tions, 13% for myocardial infarction; 22% for diabetic foot syndrome, and 12% for mortality. The annual costs of treatment of complications in DM T2 patients in Russia should decrease by US$246.7 million. **CONCLUSIONS:** The use of the human insulin analogue insulin glargine in treatment of DM T2 patients allows the cost of treatment to be decreased mainly due to a decrease in expenditures on treatment of complications.

PDB12

COSTS OF TYPE-2 DIABETES MELLITUS: A COMPARISON BETWEEN DIABETIC AND NON-DIABETIC SUBJECTS

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OBJECTIVES: Type-2 diabetes mellitus is a common chronic disease and a costly health care problem. The aims of this study were to assess the social costs of type-2 diabetes mellitus and to evaluate the costs of diabetic patients in comparison with non-diabetic subjects. **METHODS:** We conducted a Cost of Illness (COI) analysis from a societal perspective with a 3-month time horizon. Data were collected from a population based naturalistic prospective survey, designed to investigate cardiovascular risk factors in a sample of the Italian general population aged from 40 to 79 years. We selected all type-2 diabetic patients and we matched each of them by age and sex with a non-diabetic subject. Patients were interviewed by general practitioners about clinical/demographic characteristics, medical resource utilization and absence from work during the 3 months before the enrolment visit. Direct medical costs were quantified including hospitalizations, drug therapies, specialist visits, diagnostics and laboratory exams, while indirect costs were estimated based on productivity losses with the Human-Capital-approach. **RESULTS:** We studied 666 patients, 333 with type-2 diabetes matched with 333 without the disease. The mean total cost per patient-month was 228.7€ compared to 169.9€ for patients with and without type-2 diabetes mellitus, respectively (P < 0.0001). On average, direct medical cost per patient-month was estimated at 199.2€ in diabetic patients and 129.1€ in non-diabetic subjects (P < 0.0001). Hospitalizations accounted for the greatest proportion of health care costs in both groups, followed by drug therapies (hospitalizations: 65.1% and 59.6%; drug therapies: 24.5% and 29.7% in patients with and without type-2 diabetes, respectively). There was no statistically significant difference in indirect costs between diabetic and non-diabetic subjects. **CONCLUSIONS:** The results show that type-2 diabetes mellitus patients aged from 40 to 79 years are more costly than non-diabetic subjects.

PDB13

ECONOMIC EVALUATION OF THE STEPPED VERSUS ORDINARY CARE FOR PREVENTION OF TYPE-2 DIABETES IN THE JDPP: JAPAN DIABETES PREVENTION PROGRAM

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OBJECTIVES: To perform an economic evaluation for the primary prevention of typeII diabetes based on the intermediate report of JDPP. **METHODS:** At first, SF36(V.1.20) and EQ-5D with Japanese version were applied, surveying over 205 participants, to assess whether or not the stepped care in JDPP may change the QOL of the patients with the relevant symptoms of silence. The second, a decision-analytic model was used to combine transition probabilities with clinical stages of diabetes, resource use and cost data in the framework of cost-effectiveness analysis within three years since 1998. The model employed a societal perspective to estimate the expected costs for each group of the stepped vs. ordinary cares which included the direct costs