

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  $\dot{a} = 1/(1 + ri)$  was used, where  $\dot{a}$  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 provided that insulin glargine was used, in comparison to NPH insulin, would amount to 18% for microvascular complications, 25% for chronic renal insufficiency, 10% for macrovascular complications, 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

for intervention and treatment, and also production loss of patients as indirect costs. **RESULTS:** A total of 185 questionnaires on SF-36 and EQ-5D were returned (88 stepped, 97 ordinary). There was no statistically significant difference between the scores of two groups. The expected costs a patient in the decision model were estimated as US\$4072 (US\$ = JPY110) for the stepped care, and US\$2695 for the ordinary care with the discount of 3% a year in three years. The incremental cost-effectiveness ratio was US\$17,636 in terms of cost per patient prevented from becoming Type-2 diabetes. **CONCLUSIONS:** The analysis on the JDPP intermediate report suggested that the stepped care resulted in increased costs for prevention comparing to the ordinary care in three years, maintaining the same level of QOLs in both groups.

## PDB14

**COST-EFFECTIVENESS OF MONO- AND COMBINATION THERAPY WITH PIOGLITAZONE COMPARED TO GLICLAZIDE IN PATIENTS WITH TYPE-2-DIABETES MELLITUS FROM A GERMAN STATUTORY HEALTH CARE PERSPECTIVE**

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**OBJECTIVES:** Pioglitazone (PIO), a PPAR $\alpha$ -Agonist has been approved in Germany for treatment of patients with Type-2-diabetes in mono-and combination therapy with either metformin (MET) or sulfonylurea. Long-term studies with a treatment period of 104 weeks involving 1197 patients comparing PIO with Gliclazide (GLIC) have recently been published. These studies revealed a superior effect of PIO in sustaining the HbA1C reduction compared to GLIC. Whether this translates to benefits with regard to cost-effectiveness is currently unknown. **METHODS:** This study compared the clinical effects and costs of PIO (15–45 mg) combination therapy (MET) and 30–45 mg monotherapy with GLIC + MET or GLIC monotherapy, respectively. The validated IMIB Markov diabetes model was adapted. The mean time transferring a patient to insulin therapy (MIT), life expectancy (LE and  $\Delta$ LE), the related NNT to avoid 1 event/1 death and the incremental cost-effectiveness as cost per life year gained (C/LYG) discounted at 0% and 5% were calculated. **RESULTS:** In monotherapy PIO was associated with a higher MIT 11.70 vs. 11.39 years and a LE of 15.90 vs. 15.45 years ( $\Delta$ LE: 0.44 years) vs. GLIC. For PIO vs. GLIC the NNT to avoid 1 event and 1 death were 32 and 54, respectively. When leaving the C/LYG undiscounted, PIO dominated GLIC and amounted to 2997€ (5%) vs. GLIC. In combination therapy PIO + MET was associated with a higher MIT 9.73 vs. 9.23 years and a LE of 15.58 vs. 14.94 years ( $\Delta$ LE: 0.64 years) compared to GLIC + MET. For PIO + MET vs. GLIC + MET the NNT to avoid 1 event and 1 death were 28 and 36, respectively. The C/LYG for PIO + MET was calculated with 1445€ (0%) and 5480€ (5%) vs. GLIC + MET. **CONCLUSIONS:** The study indicates that PIO in mono, as well as in combination therapy, is preferable in terms of health outcomes and cost-effectiveness compared to GLIC in patients with Type-2-diabetes.

## PDB15

**A COST-EFFECTIVENESS ANALYSIS OF SWITCHING TYPE-2 DIABETES PATIENTS FROM IMMEDIATE-RELEASE METFORMIN (GLUCOPHAGE®) TO A NEW EXTENDED-RELEASE FORMULATION OF METFORMIN (GLUCOPHAGE®XR)**

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**OBJECTIVES:** Glucophage®XR is a new extended-release formulation of metformin which permits once-daily medication. Clinical studies show that Glucophage®XR demonstrate the same antihyperglycemic efficacy as immediate-release metformin (Glucophage®). However, in a retrospective chart review, patients with type 2 diabetes experienced fewer GI side effects and comparable or better glycemic control, based on HbA1C measurement, when switched from Glucophage® to Glucophage®XR. Mean HbA1c values were 7.8%-points before the switch and 7.5%-points afterwards. The CORE Diabetes Model, a peer-reviewed, validated, model was used to project the long-term cost-effectiveness of switching patients from Glucophage® to Glucophage®XR. **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 switching from Glucophage® to Glucophage®XR were derived from a retrospective database study. The analysis was performed using published UK-specific costs, health care resource utilization, clinical data and recommended discount rates of 3.5% for costs and clinical outcomes. A lifetime horizon and NHS payer perspective was taken. Only direct costs were considered. Sensitivity analyses were performed. **RESULTS:** Switching patients from Glucophage® to Glucophage®XR was projected to improve life expectancy by 0.10 years, quality-adjusted life expectancy by 0.09 years, and decrease overall lifetime costs by  $\leq$ 201/patient. Results were most sensitive to variations in assumptions about changes in HbA1c when patients are switched from Glucophage® to Glucophage®XR, and the relative costs of treatment. **CONCLUSIONS:** In real life, due to improved tolerability, compliance, and glycemic control, switching patients from Glucophage® to Glucophage®XR may improve longterm patient outcomes and lead to overall cost savings.

## PDB16

**EFFECT OF PATIENT EDUCATION IN TYPE-2 DIABETES OVER 10 YEARS BASED ON A PROSPECTIVE DIABETES MODEL IN THE PROVINCE OF STYRIA, AUSTRIA**

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**OBJECTIVES:** In the province of Styria, Austria, a structured patient education program for patients with type-2 diabetes was established in the year 2000. In this open label, prospective cohort study (n = 1150) follow-up data after one year have been analysed to document the potential effects over 10 years using the CORE-Diabetes Model, a validated, peer reviewed simulation model. Patients outcomes and total costs were calculated. **METHODS:** A Styria-wide patient education program for type-2 diabetes was established for general practitioners to improve treatment outcomes in diabetes care. The program is funded by the public health care system and a standardised documentation at baseline and after one year was used. Intermediate results after one year were incorporated in the CORE diabetes model and linked with Austria specific cost data. Monte-Carlo-Simulation (n = 5.000) over ten years projected long term effects of single patient education. A virtual control group was assumed to be treated like general Styrian diabetic population. Discount rate was 5 % annually. **RESULTS:** The average life expectancy increased by 0.29 years (7.32  $\pm$  3.48 vs. 7.03  $\pm$  3.5) under education, the total costs over ten years decreased by 774€ per patient (20,496€  $\pm$  30,335€ vs. 21,270€  $\pm$  37,917€) or 3.8%. Patient education leads to improved foot care and retinal screen-