initiation/intensification in patients uncontrolled on their current therapy. RESULTS: The median time to intensification of insulin regimen for T1 patients uncontrolled on premix regimens, was 4.0 years (95% CI 3.2 to 5.4). The median time to initiation of insulin for T2 patients, prescribed two or more oral agents, with evidence of poor glycaemic control was 7.0 years (95% CI 6.5 to 7.7). Finally, the median time to intensification of the insulin regimen was 4.2 years (95% CI 3.5 to 6.1) for T2 patients uncontrolled on a basal regimen and >8 years for those uncontrolled on a premix regimen. CONCLUSION: In spite of poor glycaemic control, insulin-naïve and insulin-treated patients fail to initiate/intensify insulin therapy for many years. Earlier initiation/intensification of insulin therapy is likely to lead to better control and a reduction in the complications associated with diabetes. Barriers to insulin use must be overcome if patients are to achieve appropriate control.

PDB35

COST-EFFECTIVENESS OF INHALED INSULIN IN PATIENTS WITH DIABETES UNCONTROLLED ON THEIR CURRENT THERAPY: THE UK BASE CASE SUBMITTED TO THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE (NICE)

Plun-Favreau J, O'Regan C, Marchant N
Pfizer Ltd, Tadworth, UK

OBJECTIVES: As part of the submission to NICE, we evaluated the cost-effectiveness of inhaled insulin (INI) in patients with type 1 diabetes uncontrolled on a premix regimen (T1), and patients with type 2 diabetes uncontrolled on oral anti-diabetic drugs (T2). METHODS: Using the perspective of the National Health Service (NHS), a validated Markov model (EAGLE) was used to estimate the incremental costs and QALYs gained of: 1) a basal bolus regimen involving INI versus an injected basal bolus regimen in T1; and 2) a bolus of INI versus i) an injected basal regimen and ii) an injected premix regimen in T2. The model simulates the progression of diabetes in 1000 patients over a time frame of 20 years. A large UK dataset was used to document the patients' clinical characteristics. NHS reference costs were used as a source for medical costs. Utility/disutility data were collected in published studies and clinical trial data were used to document the efficacy of therapies. An annual 3.5% discount rate was used for both costs and outcomes. Probabilistic sensitivity analysis was performed. RESULTS: In T1 the total incremental costs (IC) were £202,746 and the total QALYs gained (IE) were 24, leading to a mean incremental cost-effectiveness ratio (ICER) of £8510/QALY. In T2, the mean ICER versus basal was £24,285/QALY with IC of £497,749 and IE of 21. The mean ICER versus premix was £24,555/QALY with IC of £503,185 and IE of 21. The probabilistic sensitivity analysis showed that for a willingness to pay of £30,000 per QALY gained, INH was cost-effective in 100% of the T1 simulations and in 92 to 95% of T2 simulations. CONCLUSION: INH is a cost-effective therapy for T1 and T2 patients uncontrolled on their current therapy in the UK setting.

PDB36

THE TRANSLATION AND LINGUISTIC VALIDATION OF THE SATISFACTION WITH ORAL ANTI-DIABETIC AGENTS (SOADA) QUESTIONNAIRE

Houchin C1, Wild D1, Horblyuk R2
1Oxford Outcomes Ltd, Oxford, Oxfordshire, UK, 2GlaxoSmithKline, Philadelphia, PA, USA

OBJECTIVES: The objective of the study was to translate and linguistically validate the Satisfaction with Oral Anti-Diabetic Agents (SOADA) questionnaire for use in 11 countries. The questionnaire was developed in the United States in 2005 in order to assess satisfaction with oral anti-diabetic medication in patients with type 2 diabetes. METHODS: The accepted standard methodology was used: 2 forward translations, reconciliation, 2 back translations, back translation review, developer review, harmonisation meeting, linguistic validation interviews with 5 or 6 patients with type 2 diabetes and 2 proof readings. A universal approach was used for French and Spanish with the aim of developing a single Spanish and a single French version. RESULTS: While the majority of wording was easily agreed upon, certain words and phrases were more troublesome. Issues and solutions included: The first French suggestion, “medication,” did not take into account the possibility of more than one medication. The final agreement was on “medicament(s).” “Extremely [satisfied]” cannot be translated literally in Mexico as it is too formal. “Muy satisfecho” was selected as the best alternative for Mexico and Spain. “How quickly” was misunderstood in pilot testing in Korea so this was changed to a more idiomatic “the ‘fastness’.” “Tolerabilidad,” the original Spanish translation, was found to be problematic during cognitive debriefing interviews and a simpler alternative was found. The universal approach produced a single final version for French and Canadian French and very similar final translations for Spanish (for Spain) and Mexican Spanish. CONCLUSIONS: The SOADA has been translated and linguistically validated and is now available for use in 11 countries. The universal approach used for Spanish and French was successful. A number of cultural and linguistic issues became apparent and were resolved. The measure is now appropriate for use in multinational trials.
correlations of 0.41 for FC and 0.42 for RI) were good to excellent. The three scores were predictive of the unwillingness to be treated with insulin and to step up insulin treatment (AUC ranging from 0.65 to 0.87). The AM score was predictive of the switch to an insulin treatment and increased numbers of injections at the end of baseline visit (AUC of 0.80 and 0.66). CONCLUSION: The questionnaires are reliable, valid and a helpful tool for physicians in assessing the hurdles faced by diabetic patients starting or stepping up insulin treatments.

PDB38

ADHERENCE TO STATIN TREATMENT IN PEOPLE WITH TYPE 1 AND TYPE 2 DIABETES
Donnan PT, Donnelly L, Morris A
University of Dundee, Dundee, UK

OBJECTIVES: To evaluate the patterns and predictors of adherence to statin therapy in all patients with diabetes in the community. METHODS: We retrospectively studied patients with type 1 and type 2 diabetes who were resident in Tayside, Scotland from 1st January 1993 to 31st May 2003, with at least 6 months of prescriptions of statins. The main outcome measure was an adherence index. The influence of several covariates including age, sex, duration of diabetes, adherence to diabetes medication and co-morbidities were also assessed. RESULTS: A total of 5010 patients were included in the study: 4816 with type 2 diabetes and 194 with type 1 diabetes. Median statin adherence was 75% and 77% in type 1 and 2 diabetes respectively, with a similar distribution in both groups. There were 35% of type 1’s and 42% of type 2’s with adequate adherence (>80%). Predictors of adequate adherence in type 2 diabetes were being older, being an ex-smoker compared to never having smoked, better adherence to diabetic medication, a lower HbA1c level, shorter duration of statin therapy, a history of coronary heart disease, a history of stroke and being prescribed concurrent medication for cardiovascular disease. Conversely, patients prescribed concurrent asthma medication were less adherent to their statin medication. In type 1 diabetes significant predictors were being female and being prescribed concurrent medication for cardiovascular disease. CONCLUSIONS: Approximately 65% of type 1 patients and 58% of type 2 patient collected less than 80% of their medically recommended dose of statins. Given the increased risk of coronary heart disease facing patients with diabetes this poor adherence could have significant health implications.

PDB39

THE IMPACT ON QUALITY OF LIFE BY CONVERTING THE TREATMENT OF TYPE 2 DIABETIC PATIENTS FROM CONVENTIONAL INSULIN REGIMENT TO ORAL TREATMENT WITH PIODILOGLITAZONE
Greiner V1, Hodak JM2
1Universität Bielefeld, Bielefeld, Germany, 2University of Bielefeld, Bielefeld, NRW, Germany

OBJECTIVES: Conversion of type 2 diabetic patients previously treated with a conventional insulin regimen treatment to a combined oral treatment with pioglitazone and glimepiride has been shown to improve resistance and not to result in an overall deterioration of metabolic control. Thus this study was performed to evaluate the impact of this conversion on patients’ quality of life. METHODS: A sample of 116 type 2 diabetic patients (73 men, 43 women; age (mean ± SD) 59.43 ± 9.3 years) were converted as aforementioned. Quality of life was measured by using the EQ-5D questionnaire (consisting of a five-question-survey and the Visual Analogue Scale) and the disease-specific QSD-R questionnaire, both at baseline and after six months. Based on statistical analyses (descriptive statistics, paired t-test, multivariate linear regression model) factors influencing quality of life scores were identified. RESULTS: Overall high quality of life levels at baseline as well as after six month were measured. Despite these positive results both questionnaires identified problems in the dimensions “pain/discomfort” “physical complaints” and “anxiety/ depression”. The mean EQ-5D index score (based on German societal perspective) increased from 0.82 to 0.85 (p = 0.66), whereas the mean EQ-VAS score (patient perspective) increased from 70.72 to 72.88 (p = 0.235). Mean QSD-R score improved from a global stress score of 0.76 at baseline to 0.70 six months later (p = 0.223). Research results presented improvements in all dimensions measured. Multiple regression analysis as well as a subgroup-analysis demonstrated that a decreasing BMI, a lower duration of disease and male gender have a positive effect on quality of life. CONCLUSIONS: The mean quality of life scores did not change significantly. The conversion from insulin to a combined oral treatment with pioglitazone and glimepiride is possible without deterioration of health related quality of life.

PDB40

HEALTH-RELATED QUALITY OF LIFE OF TYPE 2 DIABETICS IN GERMAN PRIMARY CARE: RESULTS OF THE DETECT STUDY
Pieper L1, Klotsche J1, Jacobi F2, Pittrow D1, Bohler S1, Lehnert H3, Wittchen HU1
1Technische Universität Dresden, Dresden, Germany, 2University of Warwick, Coventry, UK

OBJECTIVES: To describe the health-related quality of life (QoL) of type 2 diabetics by age group, duration of disease, comorbidities and complications, therapeutic interventions and HbA1c status. METHODS: DETECT (“Diabetes Cardiovascular Risk-Evaluation: Targets and Essential Data for Commitment of Treatment” http://www.detect-studie.de) is a large-scale, nationally representative, cross-sectional clinical-epidemiological study with a prospective-longitudinal component in primary care. Based on a randomised sample of 3188 physicians, the health state of 55,519 patients was assessed in a standardised way in 2003. Frequency of problems in the EQ-5D items mobility, self-care, usual activities, pain/discomfort and anxiety/depression as well as the additive total score were analysed in n = 6558 type 2 diabetics. RESULTS: The most frequent QoL restrictions were in the domains of pain/discomfort (74.1%) and mobility (44.3%) followed by daily activities (34.1%), anxiety/depression (31.4%) and self-care (17.2%). The mean additive total score was 68.1. That was, after adjustment for age and gender, significantly lower than in nondiabetics (72.4) or in healthy attendees (81.7). Overall and in each QoL domain, problems increased if micro- and macrovascular disease was present, and with the age of patients or duration of diabetes respectively. There were no significant differences between patients with or without therapy (diet, exercise and oral antidiabetics). However, patients with insulin and combined therapy had considerably lower QoL scores, even after adjustment for age, gender, duration of diabetes and presence of micro- and macro-vascular disease. HbA1c adjustment had only small effects on the EQ-5D dimensions. Compared to patients with optimal HbA1c values (<6%), poorly adjusted patients (HbA1c > 8%) reported significantly more problems at the dimensions mobility and self-care. CONCLUSIONS: Our data provide, in unprecedented detail, the health related QoL of type 2 diabetics in German primary care, highlighting the association of insulin and combined treatments with reduced QoL.