≥80%. Persistence was defined as the number of days on therapy until the first 30-day gap. Propensity-score weighted logistic regression and proportional hazard models were used to adjust for baseline demographics, copay and pharmacy utilization variables. RESULTS: At baseline, across the SPAA and 2PAA groups (N = 1,530), mean age was 62 years, 49% were female, 10% utilized coronary vasodilators, 28% utilized anti-diabetics; mean number of other baseline medications was 7. These characteristics varied among all cohorts. Patients receiving SPAA were nearly twice as likely to achieve adherence, and approximately 20% less likely to discontinue therapy at all doses; compared to the European dose equivalents, the adjusted odds ratio of achieving adherence was 1.83 (95% confidence interval [CI] 1.60–2.10, P < 0.0001) and the discontinuation hazard ratio was 0.83 (CI 0.74–0.93, P = 0.0012). CONCLUSION: Single-pill amlopidine/atorvastatin was associated with greater adherence and less discontinuation vs. 2-pill amlopidine and atorvastatin, at low, high, and European doses of both medications.

CV4

BENEFIT/RISK OF IRBESARTAN/HYDROCHLOROTHIAZIDE AS FIRST-LINE TREATMENT OF SEVERE HYPERTENSION

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OBJECTIVES: Although guidelines recommend first-line combination therapy for patients with severe hypertension, no quantitative benefit/risk estimate has been provided. The objective of this study was to estimate these potential long-term benefits and risks based on results of a registrational clinical program. METHODS: Results from a clinical study in severe hypertension (diastolic blood pressure ≥ 110 mmHg) were used to project benefits and risks of irbesartan/hydrochlorothiazide (I/H) vs. irbesartan monotherapy (I). In the randomized, controlled, double-blind, 7-week trial (n = 695), initial I/H reduced exposure to severe blood pressure (BP) levels (p = 0.0003) and provided an additional BP reduction of approximately 10/5 mmHg (systolic/diastolic) compared to I (p < 0.0001 for each parameter) with similar safety. Benefit was extrapolated by using cardiovascular risks described in World Health Organization Guidelines. The BP difference between I/H and I was applied conservatively to a time frame of 0.1 to 0.8 years, as physicians in actual practice may add adjunctive therapy after the initial prescription. The potential for serious adverse events from the use of I/H were estimated based on post-marketing surveillance data (10 million patient years of exposure to I/H) and literature review. RESULTS: A population of 100,000 patients with severe hypertension is at risk for between 2,500 and 10,000 cardiovascular events in one year. Initial treatment with I/H instead of I is projected to prevent between 100 and 1,000 events in one year. No signal of potentially serious adverse events exists for I/H compared to I in post-marketing data, but an estimate of between 0 to 3 such events may be considered. CONCLUSION: The estimated benefit/risk of first-line I/H is highly favorable, even when applied to a short time horizon. This is because cardiovascular risk is the greatest issue for the patient with severe hypertension. Earlier and more extensive use of combination therapy can improve public health.

PODIUM SESSION I: ECONOMICS OF DIABETES

ED1

COST-EFFECTIVENESS OF INSULIN DETEMIR VERSUS NPH FOR TYPE 1 DIABETES PATIENTS IN A GERMAN SETTING. A MODELING EVALUATION BASED UPON RESULTS FROM A META-ANALYSIS

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OBJECTIVES: A fixed-effects (weighted average) meta-analysis of three clinical trials showed the short-term therapy benefits of treating type 1 diabetic patients (mean age 40.3 years, duration of diabetes 16.3 years, HbA1c 8.3%, BMI 25.2 kg.m-2) with insulin detemir (IDet) versus neutral protamine Hagedorn (NPH) insulin as the basal component of basal-bolus therapy when used in combination with either insulin aspart (IAsp) or human soluble insulin (HSI). METHODS: A published validated diabetes model was used to estimate the long-term cumulative incidence of complications, life expectancy (LE), quality-adjusted life expectancy (QALE) and lifetime costs for IDet versus NPH regimens. The short-term treatment effects (0.13% points lower HbA1c, a 4% decrease in hypoglycaemic events and lower body mass index 0.21 kg.m-2) observed in the meta-analyses were projected using progression data derived from landmark clinical and epidemiological studies. The costs of treating complications in the German setting were taken from published sources and total direct costs (complications + treatment costs) for each arm were projected over patient lifetimes. Both costs and clinical outcomes were discounted at 5% annually. RESULTS: The IDet arm was associated with an increase in life expectancy, compared to NPH, of 0.032 years (12.270 ± 0.130 versus 12.218 ± 0.121 years) with a resulting gain in QALE of 0.144 quality-adjusted life years (QALYs) (6.23 ± 0.07 versus 6.09 ± 0.06 QALYs) due to a reduction in diabetes-related complications. Increased treatment costs for IDet resulted in greater total lifetime costs per patient than with NPH (€91,960 ± 2,333 versus €89,367 ± 2,183, difference €2,593), leading to an incremental cost-effectiveness ratio of €18,070 per QALY gained. CONCLUSION: Short-term improvements seen with IDet versus NPH in basal-bolus therapy were projected to show improvements in both life expectancy and quality-adjusted life expectancy with a cost-effectiveness ratio which fell well within the range usually considered to represent value for money (<€50,000 per QALY gained).

ED2

LONG-TERM COST-UTILITY ANALYSIS OF INSULIN ASPART (NOVORAPID®) VERSUS HUMAN SOLUBLE INSULIN IN TYPE 2 DIABETES PATIENTS IN THE GERMAN SETTING

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OBJECTIVES: The aim of this analysis was to evaluate the cost-utility of switching type 2 diabetes patients receiving human soluble insulin (HSI) to rapid-acting insulin aspart (IAsp, NovoRapid), with or without oral hypoglycemic agents, in the German setting. METHODS: The CORE Diabetes Model, a published and validated computer simulation model, was used to project long-term clinical and economic outcomes associated with IAsp and HSI treatment effects. The model is based on 15 semi-Markov sub-models representing the most important acute and chronic diabetes-related complications including eye, renal...
and cardiovascular disease amongst others. Treatment effects and cohort characteristics (mean age 63.1 years, diabetes duration 12.8 years, HbA1c 8.17%, BMI 30.3 kg/m²) were based on the German cohort of the PREDICTIVE (Predictable Results and Experience in Diabetes through Intensification and Control to Target: an International Variability Evaluation) study. Direct medical costs were derived from published sources and expressed in 2006 Euro (€) values. Projections were made over a 35-year time horizon. Future costs and clinical benefits were discounted at 3.5% annually. Sensitivity analyses were performed.

RESULTS: Treatment with IAsp was projected to improve quality-adjusted life expectancy by approximately 0.10 quality-adjusted life years (QALYs) (6.06 ± 0.09 versus 5.96 ± 0.09 QALYs). Increased treatment costs with IAsp were partially offset by cost savings due to reductions in the cumulative incidence of diabetes-related complications. Over patient lifetimes, mean direct medical costs were projected to increase by approximately €1,274 per patient with IAsp versus HSI (€45,423 ± 1,354 versus €44,149 ± 1,391). This resulted in an incremental cost-utility ratio of €15,305 per QALY gained.

CONCLUSION: Over patient lifetimes, IAsp treatment was projected to result in fewer diabetes-related complications and improved quality-adjusted life expectancy compared to HSI. Based on currently accepted willingness-to-pay limits, IAsp would represent good value for money in the German setting.

DIFFERENCES IN HEALTH RELATED RESOURCE USE IN THE 6 MONTHS PRIOR TO AND AFTER INSULIN INITIATION IN PATIENTS WITH TYPE 2 DIABETES IN GERMANY AND UNITED KINGDOM: DATA FROM THE INSTIGATE STUDY

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OBJECTIVES: An objective of the INSTIGATE study is to describe the resource utilisation associated with care for type 2 diabetes in the 6 months before and after insulin initiation. This abstract presents data from patients enrolled in Germany and UK. METHODS: INSTIGATE is an ongoing prospective European observational study investigating patients with type 2 diabetes who have initiated insulin during usual care. Data on resource use for diabetes was collected at baseline retrospectively for the 6 months prior to initiating insulin and at 3 and 6 months following insulin initiation. RESULTS: In all, 509 patients were enrolled in Germany and UK. 6 month follow-up data was collected from 457 patients. The following changes in health care professional consultations were observed in the 6 months before and after insulin initiation: The % of patients with a visit to a primary care doctor declined from 93.4% to 83.7% in Germany, and in the UK from 79.4% to 48.2%. Visits to specialist nurses increased in Germany from 52.3% to 91.4%, and in the UK from 77.5% to 81.7 % of patients. In both countries the % of patients having phone calls with a specialist nurse increased; from 11.7% to 50.6% in Germany and from 21.3% to 75.9% in UK. The % of patients using a blood glucose monitor and the median weekly number of test strips used increased in both countries, most notably in Germany from 76.6% of patients testing 4 times a week before insulin initiation to 99.6% of patients testing 21 times per week 6 months after insulin initiation. CONCLUSION: The type of health care professionals visited and nature of the consultations changed in both countries following insulin initiation; the % of patients having visits to primary care providers decreased and the % of patients having visits and phone calls to specialist nurses increased.

THE RELATIVE COST EFFECTIVENESS OF SWITCHING TO INSULIN GLARGINE VERSUS NPH INSULIN IN INSULIN NAIVE AND NON INSULIN NAIVE TYPE 2 DIABETES PATIENTS USING UK REAL LIFE DATA

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OBJECTIVES: This study, conducted in Type 2 diabetes mellitus (T2DM), evaluated the cost utility of glargine versus NPH in previously insulin naive (IN) and non insulin naive (NIN) patients switching from NPH to insulin glargine in the UK using observational data. The study assessed the combined effect of HbA1c and hypoglycaemia reduction. METHODS: A discrete event life time simulation based on UKPDS 68 was adapted to include the effects of HbA1c and hypoglycaemia reduction using published meta-regression results from 11 randomised clinical trials. Direct costs and health utility (EQ5D) were derived from published sources and the HODar database respectively; costs and benefits were discounted at 3.5%. This model used the demographic and efficacy profiles of T2DM patients who were IN or NIN who switched from NPH to glargine identified via the THIN database. Analysis was conducted on 1,496 and 174 IN and NIN patients respectively; the primary outcome measure was HbA1c change. As hypoglycaemia was not directly collected from the THIN database, sensitivity analysis was performed taking into account HbA1c benefit only. RESULTS: The mean age and duration of diabetes at switch was 63 years and 7.5 years (IN) and 70 years and 10.2 years (NIN) respectively. After adjustment for baseline profiles IN patients starting glargine showed a significant reduction in HbA1c of 0.21% (p = 0.029) 12 months post initiation versus NPH. For NIN patients switching from NPH to glargine the adjusted HbA1c reduction was 0.46% (p = 0.0093). The cost per QALY for a simulated cohort of 10,000 patients was £5,806 and £3,415 for IN and NIN patients.

ASSESSING THE GENERALISABILITY OF COST EVALUATION RESULTS USING THE EUCLIDEAN METRIC AND PRINCIPAL COMPONENTS ANALYSIS: LESSON FROM A HIGH-COST INNOVATION IN ONCOLOGY

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OBJECTIVES: This study tested a method to measure the variability of data among countries, and to assess the generalisability of cost evaluation results. METHODS: The first step of the method consisted in identifying, within cost evaluations, all the factors potentially responsible for variability among locations. The second step consisted in selecting, among all potential transferability factors, the final transferability factors which generated variability, impacted on outcomes of economic evaluation, and were both measurable and distinguishable from other factors. The third step was the identification of transferability areas as sets of homogeneous final transferability factors. Both the Euclidean metric and Principal Components Analysis were used in the fourth step to explore the generalisability of the results.