heart failure, and non-fatal stroke. RESULTS: The ACE/CCB-combination showed a beneficial effect on HbA1c values, and the resulting event rate in this group is lower than for patients treated with fixed combinations like atenolol/chlorthalidone or enalapril/hydrochlorothiazide. Extrapolating data from one study, the relative risk was lowered by 20% for most diabetes-related events in comparison to atenolol/chlorthalidone. “Cataract extraction” and “renal failure” were reduced by 19%, “blindness” by 30%. The risk reduction for CVD amounted 13% for non-fatal myocardial infarction, 12% for non-fatal stroke. In the second study, the relative risk for “Cataract extraction” is reduced by 16% in the ACE/CCB-group after 10 years, compared to the patient group treated with a combination enalapril/hydrochlorothiazide. The risk reduction for CVD amounted 17% for non-fatal myocardial infarction and 16% for non-fatal stroke. CONCLUSION: The use of this computerized model allows gaining insight into the long-term medical outcomes of the treatment with ACE/CCB-combination in hypertensive type-2 diabetics. The model shows a beneficial effect for the combination trandolapril/verapamil in diabetic patients because of the additional HbA1c decreasing effect beside the hypertension management.

**PDB6**

**RETROSPECTIVE STUDY EVALUATING CLINICAL AND ECONOMIC OUTCOMES OF MONOTHERAPY VERSUS DUAL THERAPY IN DIABETIC PATIENTS IN A COUNTY HEALTH CARE SYSTEM**

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OBJECTIVE: The primary objective is to evaluate the clinical and economic outcomes of monotherapy with a sulfonylurea versus dual therapy with metformin and a sulfonylurea in a county health care system. METHODS: This is a retrospective, chart-review, study in which the patients will serve as their own controls, prior to starting dual therapy. All patients are evaluated two years prior to and post the addition of the second agent, metformin. Data collected will include the following: HbA1C, fasting blood glucose, lipid profile, and liver and renal function tests, adverse drug reactions, number of hospital and emergency room admissions, number and type of clinic visits, and number of operations/procedures/and diagnostic tests. The t-test for paired data is utilized to analyze the continuous variables. RESULTS: A total of 124 patients enrolled in this study, with a mean duration of diabetes of 6.68 years (SD 4.62). The average HbA1c on monotherapy is 10.5% versus 10.2% on dual therapy (NS). The average fasting blood glucose is 229mg/dL on monotherapy versus 192mg/dL on dual therapy (p < 0.05). For the economic outcomes on monotherapy there is an average of 1.31 visits per patient versus 1.43 visits on dual therapy to the emergency room, hospital, and to ambulatory care clinics. On monotherapy, 31% of the patients had procedures and 37% had diagnostic tests, compared to 38% and 51% respectively, on dual therapy. CONCLUSIONS: This study does point to better clinical outcomes with dual therapy; however, there is a concurrent rise in the resource utilization. This increase could be due to more education on the physician side for preventive practices and to an increase in the patient access within the system. More research, especially prospectively designed studies, need to be conducted to determine the exact clinical and economic impact of dual oral therapy for diabetes.

**PDB7**

**THE WHO/IDF CARECARD DIABETES AS AN INTERNET-BASED APPROACH FOR QUALITY ASSURANCE IN SWITZERLAND**

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OBJECTIVE: Implementing an internet-based managed care model for diabetes care in Switzerland. METHODS: The CareCard Diabetes is a national standard for diabetes care in Switzerland. In a joint approach the largest Swiss health insurance and an urban general practitioners’ association have launched a joint quality assurance initiative for diabetes care in Luzern. An Internet quality assurance database is used to connect the physicians. Data from the CareCard were supplemented with specific anamnestic data and information regarding diabetes medication in order to allow for cost-effectiveness and risk analyses. The data are presented to the physician in several ways. Most important is a weighted problem list as a feedback to the GP, which gives advice on how to improve the diabetes care for each patient. The diabetic has access to the online CareCard Diabetes and via web-interface or call-center, and the entry of self-control data is possible. The physician in return has access to the self-control data of the patient and can derive information for the optimisation of the therapy. Quality campaigns help to facilitate the use of the system and to promote widely accepted guideline knowledge into routine diabetes care. A proof-of-concept study in Luzern has started in June 2001, with currently 176 patients being enrolled. RESULTS: HbA1c values decreased in type 2 diabetes patients from 7.3% to 6.9% (p < 0.05). Men initially had worse HbA1c levels and showed greater improvements ~0.5% than women did ~0.2% (p < 0.05). Results from an additional HbA1c quality assurance campaign found a relevant deviation of practice measured HbA1c levels (mean 6.9 % +/- 1.4%) in comparison to reference laboratory measurements (mean 7.3 % +/- 1.4%). The study will end in June 2003.
CONCLUSION: The CareCard Diabetes was found to be an up-to-date standard for implementing a quality of care initiative in Switzerland. The internet offers possibilities to extend the value of this originally paper-based tool for improving quality of diabetes care.

TYPE-2 DIABETES AND BODY MASS INDEX (BMI): WHAT CAN WE LEARN FROM A LONGITUDINAL DATABASE STUDY?
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OBJECTIVES: Type-2 diabetes increases the risk of cardiovascular and cerebrovascular complications. In general population, overweight/obesity are associated with high risk of related diseases. In a type-2 diabetes patient’s population, we examine the relationship between BMI status and incidence of cardiovascular and cerebrovascular complications. METHODS: We used a cohort of type-2 diabetes patients over a 15-year period. Study patients were stratified in 4 BMI groups: 20–24.9 kg/m² (normal weight), 25–29.9 kg/m² (overweight), 30–34.9 kg/m² (obese) and over 35 kg/m² (very obese). Incidence of diseases was analyzed retrospectively in each BMI group relative to the “normal weight” group. RESULTS: Five thousand four hundred and thirty five type-2 diabetes patients were examined. Average age was 63.61 years and 44% of the population was women. Number of patients per group were 1,060 normal weight, 2,072 overweight, 1,454 obese and 849 very obese. Average follow-up (734 days) and average duration of diabetes history (15 years) were comparable in each BMI group relative to normal weight group. Incidence of myocardial infarction are 1.13%, 4.05% (p < 0.05, Chi2), 2.48% (p < 0.05, Chi2) and 1.53% (p > 0.05, Chi2); incidence of coronaryography are 0.57%, 1.40% (p < 0.05, Chi2), 1.65% (p < 0.05, Chi2) and 1.77% (p < 0.05, Chi2), respectively in normal weight, overweight, obese and very obese. PTCA and CABG are more frequent in obese group compare to normal weight. HbA1c is normalized (below 7%) in higher proportion of normal weight patients (21.89%) compare to obese (18.50%, p < 0.05, Chi2). Incidence of cerebrovascular events such as stroke or TIA are not statistically different according to BMI group. CONCLUSION: In this analysis, variables like follow-up and duration of diabetes history were homogeneously distributed among BMI groups. In this cohort of type-2 diabetes patients, we observed that cardiovascular events are more frequent in overweight/obese compared to normal weight. Further research will need to confirm that a relevant weight reduction would have a clinical benefit in this high-risk patients population.

DIABETES—Quality of Life/Preference

DEVELOPMENT AND VALIDATION OF THE INSULIN TREATMENT SATISFACTION QUESTIONNAIRE (ITSQ)
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OBJECTIVES: Patient reported Treatment Satisfaction instruments can be used to assess degree of acceptability and effectiveness of a treatment. For diabetes, this assessment can be helpful for guiding treatment decisions about the most optimal insulin therapy regimens for a given patient. Unfortunately, there are no instruments identified in the literature that assess the full spectrum of satisfaction issues with insulin therapies. Therefore, we undertook the development and validation of the comprehensive Insulin Treatment Satisfaction Questionnaire (ITSQ). METHOD: An original item pool was developed using data collected from five focus groups with insulin users, current literature and consultation with behavioral diabetes researchers. The initial questionnaire was tested in 170 diabetes patients from 3 large clinical centers in different regions of the US who were currently using a variety of insulin regimens. A confirmatory psychometric study in 402 insulin users was subsequently conducted. RESULTS: Item and scale analysis with IRT and factor analysis resulted in the identification of six subscales: Ease/Convenience, Interference, Lifestyle, Hypoglycemia, Glycemic control, and Insulin Delivery System. Cronbach alpha reliability ranged from .79 to .92, and 2-week test-retest reliability (n = 35) ranged from 0.65 to 0.89. Convergent validity of the ITSQ was established in relation to several questionnaires, including the PAID, insulin self-efficacy and diabetes symptoms questionnaires. The ITSQ subscales discriminated significantly for A1c level, Type 1 vs. Type 2 diabetes, and global satisfaction. The confirmatory validation study confirmed the original six-factor structure and the discriminative validity. The final shortend ITSQ contains 25 items, which may be reported as a total score or as 6 subscale scores. CONCLUSION: The ITSQ is a comprehensive and psychometrically valid instrument covering six distinct dimensions of treatment satisfaction with insulin. It is applicable to type-1 and 2 diabetes patients and a wide range of insulin regimens.