and MTG patients. Additionally, hospitalizations in intensive care units (50% SG vs. 22% MTG patients), emergency visits (21% SG vs. 6% MTG) and the presence of adenoma complications (73% SG vs. 44% MTG) constitute a source of cost increment in these patients. Patients who accomplish with the most strict study clinical control criteria (GH < 1.0 and IGF-1 < 100%) showed the lowest direct cost of treatment ($6169 vs. $12,990). CONCLUSIONS: The economic cost of acromegaly is therefore dependent on the clinical control of the disease. Direct cost of illness is the half that the cost in non-controlled patients.

**PD85 APPROVAL AFTER REJECTION—AN INSIGHT IN HTA RE-EVALUATIONS**

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**OBJECTIVES:** To gain insight into the re-evaluation process of HTA agencies after an initial rejection and identify the adaptations that led to the approval of re-submitted dossiers. **METHODS:** Phase I: manual search of 57 health care agencies’ websites for published diabetes-related assessments (January 2007-June 2010). Phase II: the two most re-assessed drugs for which detailed information was available were selected for further evaluation (insulin glargine and exenatide). For these drugs, all reports published prior to 2007 were also included. **RESULTS:** Phase I identified 117 relevant single technology appraisals; 18 were re-evaluations. Six agencies performed re-evaluations of the same drug after an initial rejection: CADTH, CVZ, HAS, PBAC, AHTAPol and SMC. To date, SMC evaluated 32 submissions for 13 anti-diabetic drugs, PBAC published 20 (eight drugs), CADTH 13 (four drugs), CVZ 14 (four drugs) and AHTAPol 10 (two drugs). In phase II insulin glargine (four re-submissions to PBAC and 1 to CADTH) and exenatide (two re-submissions to PBAC, 1 to CVZ and 1 to AHTAPol) were evaluated. It became clear that payers do focus on overall cost. The approach that was chosen for those two drugs was to control overall cost either by restricting access or by setting on a lower price. CVZ accepted exenatide for reimbursement only after restricting access to a subgroup of obese type 2 diabetes mellitus patients (with an ICER of €5,231). Instead of insulin glargine PBAC insisted on lowering the price for both medications (rationale for insulin glargine being concern that prescribing cannot be contained within the defined population). AHTAPol limited exenatide reimbursement to 50% to control prescribing rates. **CONCLUSIONS:** For the diabetes case analyses HTA agencies attempted to control health care expenditure by either lowering drug costs or by narrowing the definition of the target population, the latter inevitably allowing fewer patients access to the drug.

**PD86 HEALTH TECHNOLOGY ASSESSMENT OF DIABETES COMPOUNDS: THE POLISH PERSPECTIVE**

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**OBJECTIVES:** The AOTM in Poland was established to give MoH in Poland advice on reimbursement. The aim of this research is to create an overview of HTA reports on diabetes compounds in Poland and the results of the decision making. **METHODS:** A search was conducted on the webpage of AOTM (http://www.aotm.gov.pl) for HTA reports on the following products: Rosiglitazone, Pioglitazone, Stagliptin, Vildaglaptin, Saxagliptin, Exenatide, Liraglutide, Glargin, Detemir, Aspart, Glulisene and Lispro. **RESULTS:** Of a total of 163 reports (published between 2007 and 2010), eight reports vs. 1.0 and IGF-1 were evaluated. Patients who accomplish with the most strict study clinical control criteria (GH < 1.0 and IGF-1 < 100%) showed the lowest direct cost of treatment ($6169 vs. $12,990). CONCLUSIONS: The economic cost of acromegaly is therefore dependent on the clinical control of the disease. Direct cost of illness is the half that the cost in non-controlled patients.

**PD87 STANDARDS FOR THE ASSESSMENT OF ANTIDIABETIC DRUGS—THE IQWIG PERSPECTIVE**

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**OBJECTIVES:** A substantial number of new pharmaceutical treatment strategies have been introduced for the treatment of diabetes mellitus type II. The availability of these drugs for patients in different countries depends on the evaluation standards and methods applied in the various phases of drug assessment. Objective of this research was to review the requirements and criteria applied for the assessment of antidiabetic drugs along the regulatory process by EMA (Europe) and FDA (USA) for the assessment of efficacy and safety as well as for reimbursement decisions by NICE (England) and IQWIG (Germany) and to compare their consistency, with a special focus on IQWIG’s procedures. **METHODS:** A review of relevant current method documents and reports on evaluations of antidiabetic drugs published by IQWIG was conducted. These were compared with guidance documents issued by FDA, EMA and NICE with respect to endpoints considered in diabetes and their definition, criteria for the type of evidence, and potential comparators. **RESULTS:** Consistently, across all agencies newer and non-severe hypoglycaemia were considered highly relevant. There was, however, a substantial heterogeneity in the definition of hypoglycaemias. The surrogate parameter HbA1c, as primary endpoint was accepted by all agencies investigated apart from IQWIG. In its assessments, evidence from randomized as well as from observational studies was accepted by NICE. For safety evaluations precursors and possible effects were taken into consideration by EMA and FDA in addition to randomized controlled trials. IQWIG on the other hand focused exclusively on randomized controlled trials for the assessment of effectiveness as well as safety. **CONCLUSIONS:** There is a substantial variation of criteria applied and evidence considered relevant within the assessment process of IQWIG compared to other agencies. This might lead to regional variations in the availability of drugs. It is important to be aware of the different requirements of agencies, when designing trials and planning market access.

**PD88 LEARNING FROM DISEASE MANAGEMENT PROGRAMMES: HOW MEDICAL TREATMENTS AND QUALITY OF DIABETIC CARE (TYPE II) IN GERMANY ARE DIRECTLY AND INDIRECTLY IMPROVED BY DMPs**

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**OBJECTIVES:** Disease Management Programmes (DMP) aim at improving care quality by implementing standard methods for medical practices. In the case of Diabetes Mel- litus Type II (DM II), care improvements can be assessed by the first diagnosis and the occurrence of the first related complication. The aim of this longitudinal study is to investigate the direct influence of the DMP-based treatments on patient outcomes, measured as the postponement of diabetes related complications in a large population of DM II patients. The study also investigates how DMP inscrip- tions of some patients of a medical practice indirectly influence patient outcomes of DM II patients, who are not inscribed in a DMP, but are treated in the same practice. We argue that this indirect effect is due to physicians’ learning from the DMP-based experiences of their colleagues in the medical practices. **METHODS:** Using consultation data from IMH for a period from a period of 25 years (1984-2009) a survival analysis is applied. The dataset includes 161,747 DM II patients from >1100 practices. Applying a Kaplan–Meier– Method we test for direct effects of DMPs on patient outcomes. By pooling patients by physicians born in the year of practice the leading physician and by focusing on their quarterly consultation rate, we test for indirect effects of DMPs on patient outcomes. **RESULTS:** The mean survival time (duration between first diagnosis and first compli- cation) of the medical treatment of diabetics in a DMP is 14,82 years, differing signifi- cantly from the 15,76 years without a DMP. These tests are followed for patient variables: sex, age, HbA1C, BMI and the insurance status. Learnings from DMPs, indirectly affecting DM care, significantly postpone complications for younger physicians and practices with fewer diabetics. **CONCLUSIONS:** Contributing to assessments of DMPs, the study discusses policy implications, as it is shown that care quality is improved by physicians learning from DMPs.

**PD89 PREDICTORS OF ROUTINE MONITORING OF DIABETES CARE AMONG THE US NON-INSTITUTIONALIZED POPULATION: A RETROSPECTIVE ANALYSIS OF THE MEDICAL EXPENDITURE PANEL SURVEY (MEPS) IN 2007**

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**OBJECTIVES:** To examine the rate and predictors of diabetes monitoring in the US. **METHODS:** This cross-sectional retrospective study was conducted on a representa- tive, non-institutionalized sample of the US population, using the self-reported infor- mation from the 2007 Household Component (HC) of the MEPS. According to the American Diabetes Association (ADA) 2007 practice guidelines, providing proper monitoring is defined as at least two A1c tests, one eye and one foot examination annually. Health status was measured by SF-12 Version 2. A logistic regression model was used to examine the predictors of proper monitoring. Differences in health status and medical expenditures between patients with and without proper monitoring were examined using t-tests. Estimates were weighted to the total population (WTP). **RESULTS:** Among 1,747 (WTP: 19,320,394) patients with diabetes, 80.64% had at least two A1c tests; 63.29% had an eye examination; and 67.5% had a foot examina- tion. 61.36% of patients (WTP: 41,065,249) received proper medical treatment. Older patients (OR:1.021, 95% confidence interval [Cl]: 1.021–1.030), non-Hispanic Caucasians compared with African American patients (OR: 1.236, 95% CI: 0.933– 1.636), patients with a higher education level (OR:1.211, 95% CI: 1.056–1.390), insurance coverage (OR:2.216, 95% CI: 1.408–3.486), use of oral anti-diabetic drugs (OR:2,935, 95% CI: 2.131–4.042) and insulin (OR:3.453, 95% CI: 2.477–4.814) were more likely to undergo the proper monitoring. Well monitored patients had a higher Mental Component Summary score (30.09 ± 0.37 vs. 48.31 ± 0.43, P > 0.05), but a lower Physical Component Summary score (39.95 ± 0.34 vs. 42.28 ± 0.47, P <
0.05) on the SF-12. Properly monitored patients spent significantly more on total health care services ($5243), outpatient visits ($1023), and medications ($1204), respectively (all P-values<0.05). CONCLUSIONS: In the US, nearly 40% patients with diabetes do not receive the proper diabetes monitoring controlling for racial and socioeconomic disparities. Anti-diabetic/insulin use, mental/cognitive status, physical health status, and health care expenditure may also interact with performing monitoring. Barriers and cost-benefit for long-term monitoring should be studied.

DIABETES/ENDOCRINE DISORDERS – Conceptual Papers & Research on Methods

CLINICAL AND ECONOMIC CONSEQUENCES OF THE PHARMACOLOGICAL HYPOGLYCEMIC TREATMENT OF TYPE 2 DIABETES IN CROATIA

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OBJECTIVES: Diabetes mellitus type 2 (T2DM) is a chronically progressive disease and the treatment must be selected according to the pathophysiological phase of the disease. At the time the treatment is begun. The Croatian public diabetes sector takes care of approximately 150,000 adults treated with oral hypoglycemic agents (OHA) alone or in combination with insulin. Our objective was assessment of the clinical and economic consequences of OHA treatment in T2DM from a Croatian health care system perspective.

METHODS: The target population defined for the study was diabetic patients treated with OHA alone. Medication consumption was quantified by using Pharmis and CroDiab data, a clinical expert panel provided resource-use information not available in published literature or health care databases.

RESULTS: Current consumption data is showing that 62.8% patients are using OHA as monotherapy. Within this group, majority is using either biguanides or sulphonylureas. Patients treated with sulphonylureas are represented with almost the same percentage as those treated with biguanides (25% vs. 29%). Combination of two OHA is used in 34.2% while 3% of patients are treated by triple therapy. The most often chosen in dual therapy is combination of biguanides and sulphonylureas while biguanides, sulphonylureas and thiazolidinediones in combination as the most favourable treatment option in triple therapy. Biguanides are used as a one of OHA in 61% of patients.

CONCLUSIONS: Considering current clinical guidelines, lifetime benefits of biguanides and facts that they are low-cost agent, relatively small proportion of T2DM patients are treated with this agent in Croatia. Findings of this investigation revealed real life pattern of T2DM treatment, which enables directing in better treating and more cost-effective management in Croatia.

THE RELIABILITY OF PROPORTION OF DAYS COVERED: CALCULATIONS USING DEFINED DAILY DOSE ESTIMATES

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OBJECTIVES: Using a large, US administrative pharmacy claims database, calculate the proportion of days covered (PDC) of actual days supplied (PDC) using days supply derived from drug-specific Defined Daily Dose (DDD) criteria. METHODS: Continuously eligible patients filling non-insulin anti-diabetic medication were targeted from a large sample of pharmacy claims during 2008 and 2009. Medications were grouped into ATC diabetes drug classes. Proportion of days supplied (PDC) was calculated as the number of days a patient had medication in their possession divided by the number of days in the period. PDC was first calculated using actual days supply, then PDC was calculated using an estimated days supply from DDD, strength, and pill quantity. The percent of patients adherent to therapy was defined by a PDC > 0.80. The reliability of each method was assessed by Pearson correlation coefficients and agreement above chance was assessed using Kappa statistics.

RESULTS: Adherence was calculated for 163,150 patients taking non-insulin antidiabetics. Overall, the PDC and DDD were highly correlated. Two measures were also highly and significantly correlated (r = 0.73; P < 0.0001). The percent adherent was 48.8% (PDC) and 34.4% (DDD), (Kappa = 0.50; P < 0.0001). At the medication class level, differences in PDC and DDD ranged from 0.01 to 0.35, with correlation coefficients ranging from 0.40 to 0.74. Differences in the percent adherent metric ranged from −2.3 to 23.2, and kappa values from 0.22 to 0.89. CONCLUSIONS: Applying DDD estimates for the purposes of diabetes adherence estimation when lacking days supply values may provide reasonable estimates of adherence based on results presented here. At the medication class level there is greater variability in the reliability measures. Including claims from the US only is a limitation of this analysis, as local treatment patterns may vary, and DDD values were not available for all U.S. medications.

DIABETES/ENDOCRINE DISORDERS – Conceptual Papers & Research on Methods

MARKOV AND MONTE-CARLO MODELS IN THE PROGRESSION OF DIABETES MELLITUS: A LITERATURE REVIEW TO IDENTIFY THE FACTORS INFLUENCING THE CHOICE OF THE TYPE OF MODEL

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OBJECTIVES: Markov and Monte-Carlo models have been used to simulate Diabetes Mellitus (DM) and its complications over time, but reasons to choose the model type are poorly documented. A systematic literature review was performed to identify factors influencing the choice of the model type.

METHODS: Models simulating the progression of DM and its complications were selected from Medline and Embase databases. Literature reviews, methodological articles and non original models were excluded. Each full-paper selected went through a 31-item checklist via a double-reading process. A qualitative analysis was performed to evaluate the accuracy of the model with the study question.

RESULTS: Sixty-one models were selected, including

TREATMENT PATTERNS AND ACHIEVEMENT OF THERAPEUTIC GOALS IN A COHORT OF TYPE 2 DIABETES MELLITUS PATIENTS TREATED IN THE BRAZILIAN PRIVATE HEALTH CARE SYSTEM (PHCS): INITIAL REPORTS OF DIAPS 79 STUDY

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OBJECTIVES: The Texas Newborn Screening Performance Measures Project was initiated with the objective of developing evidence-based performance measures to improve quality, accountability and uniformity in the care. METHODS: A three step approach was used for identification and development of key measures for seven most critical pediatric disorders (newborn screening disorders, phenylketonuria, sickle cell anemia, and others). Key measures were evaluated and scored by clinical experts in the field using a Likert scale. Key measures with a score higher than 3 are recommended for inclusion in the QM model. RESULTS: A total of 50 performance measures were supported by scientific evidence. Impact and feasibility assessments led to the approval of 33/50 measures. “Time to initiate treatment” received the highest score (76). Other measures with potentially high impact (score >60) were: compliance with oral prophylactic medication and age at first Prevnar® vaccination in sickle cell disease; screening of at-risk family members in fatty acid disorders; frequency of growth assessments in congenital adrenal hyperplasia and phenylketonuria. CONCLUSIONS: This is one of the first efforts to identify and develop evidence-based performance measures in newborn screening and can pave the way for system wide changes and developments of national guidelines.

PHARMACOLOGICAL HYPOGLYCEMIC TREATMENT OF TYPE 2 DIABETES MELLITUS: A LITERATURE REVIEW TO IDENTIFY THE FACTORS INFLUENCING THE CHOICE OF THE TYPE OF MODEL

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