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 clinical control criteria (GH<1.0 and IGF-1<100%) showed the lowest direct cost of treatment ($618 vs. $12,990). CONCLUSIONS: The economic cost of acromegaly is dramatically high 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-May 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, PHAC, 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 settling 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 patient segmentation PBAC insisted on lowering the price for both medications (rationale for insulin glargine being concerned that prescribing cannot be contained within the defined population). AHTAPol limited exenatide reimbursement to 50% to control prescribing rates. CONCLUSIONS: For the diabetes cases analyzed 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 diabetes were identified and assessed. Two reports can be viewed as secondary assessment of regulatory safety discussions. The other six reports assessed the safety concerns associated with diabetes mellitus type 2 (DM2) 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 severe and non-severe hypoglycaemias were considered highly relevant. However, there was, however, a substantial heterogeneity in the definition of hypoglycaemias. The surro- gate 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 predefined hypoglycaemia cut-points 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.

**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 severe and non-severe hypoglycaemias were considered highly relevant. However, 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 predefined hypoglycaemia cut-points 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 standards for medical practices. In the case of Diabetes Mel- litus Type II (DM II), care improvements could be assessed by the first day of care, 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 of a patients 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 improvements in their clinics. METHODS: We used the data from a period from a period of 25 years (1984-2009) a survival analysis is applied. The data set 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 at the year of the practice-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 sig- nificantly from the 15,76 years without a DMP. These tests are followed for 25 patients: 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, proper monitoring is defined as at least two A1c tests, one eye and one foot examination annually. Health status was measured by SF-12 Version2.3, 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 67.51% had a foot examina- tion. Older patients (OR:1.021, 95% confidence interval [CI]: 1.012-1.030), 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 ± 0.47, P <