baseline and 3 months in 344/383 patients who took ≥1 dose of study drug. Patients were included if they were ≥18 years old and had diabetes (HbA1c ≥7.7% [53 mmol/mol] and ≥80% of days with HbA1c ≥7.7%) and were not taking an insulin. HbA1c was 9.1% (±1.5) at baseline and 8.3% (±1.2) after 3 months; 11.6% reached HbA1c ≤7%. The mean insulin dose at 3 months was 38.6 IU (±28.0). A cluster of 4 factors that favourably affected glycemic control was identified: TZDM, lower baseline HbA1c, 1 hypoglycaemic event, and being Caucasian. Patients with TZDM and those with a history of cardiovascular disease or those taking at least two cardiovascular medications were less likely to experience hypoglycaemia compared with the therapeutic and pharmacoeconomic point. To see the influence of pharmacotherapeutic and pharmacoeconomic aspect of use of hypoglycemic drugs when compared with the

**OBJECTIVES:**

To assess the characteristics of type 2 diabetes patients treated with vildagliptin (a new DPP-4 inhibitor) and to evaluate potential mis-use, treatment adherence, effectiveness and tolerability of vildagliptin under real-life conditions of care in France. **METHODS:** Following a request by the French Health Technology Agency (Haute Autorité de Santé) an observational cohort study was started in 2010. The study population included a representative sample of patients with type 2 diabetes initiating a treatment with vildagliptin. Patients were enrolled through a national sample of vildagliptin prescribers. Data collected included sociodemographic characteristics, clinical history, comorbidities, detailed treatment and laboratory data, physical exam and adherence. **RESULTS:** Overall, 482 GPs and 84 endocrinologists enrolled 1702 patients. Sixty percent were males, mean age was 64.2 years, 68% were overweight and 7% were smokers. Mean disease duration was 11.1 (±4) years, mean HbA1c was 9.1% (±1.5) at baseline and 8.3% (±1.2) after 3 months. Forty-five percent were obese and 39% were overweight. Seventy percent were treated for hypertension and 66% for dyslipidaemia, and 1256 patients (74%) were treated with vildagliptin/metformin fixed combination (Eucerias, FC) and 442 (26%) with vildagliptin (Galvus). Main reasons for initiating vildagliptin were: previous treatment failure (82%), weight gain (17%), reducing the numbers of pills (16%) and intolerance to a previous treatment (12%). In accordance to the precautions of use, 1366 patients (80%) underwent liver function tests, and 1552 patients (91%) blood creatinine measurement prior to treatment initiation. In few cases, vildagliptin was used for patients for whom the product was not recommended: at baseline, 21% of treated patients presented elevations in alanine/aspartate aminotransferase ≥3× the upper limit of normal, 0.3% a NYHA class III congestive heart failure (no class IV) and 9.3% did not respect the precautions of use for renal function impairment. **CONCLUSIONS:** Most of the prescriptions of vildagliptin were in accordance with the summary of product characteristics in this large, randomly selected French population.

**PD1B**

**ASSESSMENT OF THE CLINICAL AND ECONOMIC BENEFITS OF ADEQUATE INSULIN INITIATION AND INTENSIFICATION IN PEOPLE WITH TYPE 2 DIABETES MELLITUS**

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**OBJECTIVES:** To assess the clinical and economic benefits associated with adequate and early insulin initiation and intensification in people with TZDM. **METHODS:** A systematic review was performed using published papers from January 2000 to August 2010 that assessed intervention, disease, study design and outcomes. Studies were classified as initiation and intensification based on predefined criteria. Individual studies from systematic reviews and meta-analyses identified in our review were searched and included if relevant. **RESULTS:** We screened 2690 articles, of which 76 (40 initiation and 36 intensification) studies were included. Baseline HbA1c values were in all initiation studies >8.5%. Endpoint HbA1c in all intensification studies, with 2% end-point HbA1c were seen with the intensification studies (endpoint HbA1c ranging from 6.4% to 9.6%). Addition of insulin to oral anti-diabetic agents (OADs) resulted in better glycaemic control in most studies. Blood pressure levels reduced substantially with OADs + insulin compared to OADs alone. Quality of life outcomes and treatment satisfaction were reported in six studies and not significantly different for insulin versus OADs. Hypoglycaemic events were lower with insulin initiation versus OADs (1.39 ± 1.16 vs. 2.35 ± 0.79). However, all insulin types were associated with weight gain though the comparison with OADs elicited varying results. Economic outcomes were reported in four studies with insulin initiation. Some studies reported a reduced incidence in diabetes-related complications with insulin, resulting in lower diabetes-related medical and total healthcare costs in these patients. Two studies showed that initiating insulin in these failing OADs resulted in increase in life expectancy and quality-adjusted life expectancy. **CONCLUSIONS:** Proactive management of uncontrolled glycaemia in people with TZDM should be considered with early insulin initiation and intensification. Further studies are required to explore the economic benefits with early insulin initiation and intensification.

**PD1C**

**OFF-LABEL AND NON-LICENSED ENDOCRINOLOGY MEDICINE USE IN TURKEY: A RETROSPECTIVE ANALYSIS OF COMPUTER RECORDS IN THE TURKISH MINISTRY OF HEALTH**


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**OBJECTIVES:** Off-label is defined by the Turkish Ministry of Health (MoH) as the use of licensed pharmaceutical products in doses outside of or exceeding the scope of the registered indication, and the use of non-licensed but imported medicinal products for the purpose of individual treatment. The use of off-label or non-licensed endocrinology medicines were evaluated in order to provide an understanding of Turkey’s perspective within this area of healthcare provisioning. **METHODS:** A computer search was performed of IEGM’s database. A patient base using off-label endocrinology medicine applications from 19 June 2009 to 19 June 2010 were reviewed. **RESULTS:** The computer search for the found 357 applications submitted for off-label endocrinology medicine use. It was concluded that the highest application percentage was established by “osteoporosis” in all of the applications (43%, 155/357). The highest application was established by Ankara province (28%, 44/155). University hospitals had the highest off-label osteoporosis medicine use applications (66%, 155/238). **CONCLUSIONS:** It could be said that off-label use can lead to reimbursement restrictions in endocrinology, especially for teriparatide-like oncology medicines. In Turkey, physicians who want to prescribe an off-label or non-licensed pharmaceutical or a medicine which has a different use from reimbursement indications, need to apply through the off-label medicine use process.
tically significant for both feet (p<0.003). Hyperkeratosis of both feet, evaluated by the doctor, significantly improves after 4 weeks of treatment. The efficacy score measured in inches has increased (4.8 ± 4.8) on inclusion. Measured under the same conditions, it is 7.7 (± 3.2) at 4 weeks. The difference is statistically significant (p<0.001).

Treatment compliance is good since 97% confirm that they respected the dosage, a trend confirmed by the fact that 94% of subjects say that they are satisfied with the results. CONCLUSIONS: By means of a validated score (KAI) and an efficient evaluation scale, the efficacy of PediMed in treating the diabetic foot is confirmed.

PDB19
PREVALENCE OF DIABETES MELLITUS AMONG PATIENTS WITH VASCULAR COMPLICATIONS IN POLAND
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OBJECTIVES: The objective of this study was to estimate a prevalence of diabetes mellitus identified by literature search showed that DM was diagnosed in 22% of patients with unstable angina and 22% patients with ESRD. The results of two studies regarding Polish population indicate that 15.3% of patients with stable angina pectoris suffer from DM. The results of studies coming from European countries, which were identified by searching medical databases and Polish registries. Publications were selected in a specific order, to ensure that included data are the most representative for Polish population. Firstly, studies conducted in Polish settings were included and, if no reliable publications were found, European, non-European Caucasian and other (not specified) population were analyzed. Population based registries were considered as the most appropriate type of data. When no registry was available systematic reviews of observational studies were included. If systematic review was not available – data from clinical studies were taken into account. RESULTS: According to polish registries, DM was present in 28.9% of 2,683 matched pairs. Matched cohorts were compared using paired t-tests and nonparametric tests as appropriate. The effectiveness endpoints were changes in A1C (primary endpoint), weight, body mass index (BMI), blood pressure (BP), lipid levels, and hypoglycemia rates. RESULTS: The matched exenatide and glargine (n=1,156) cohorts achieved greater mean (± SD) reduction in A1C (0.66% ± [1.5] versus 0.41% ± [1.7], P<0.01), weight (2.6 [6.8] vs. -0.2 [-9.2] kg, P=0.01), BMI (0.9 [2.6] versus -0.1 [-2.7] kg/m², P<0.01), and systolic BP (1.8 [17] vs. -0.3 [-18] mmHg, P<0.01). More exenatide-treated patients reached the A1C goal of <7% (46% vs. 36%, P<0.01). There were no clinically significant differences in diastolic BP, lipid levels, and hypoglycemia rates between cohorts. CONCLUSIONS: Exenatide-treated patients experienced significantly greater reductions in A1C, weight, BMI, and systolic BP than the glargine cohort. These results demonstrated the clinical effectiveness of exenatide compared to glargine in a large, diverse, ‘real-world’ patient population treated in the ambulatory care setting.

PDB20
A1C VARIABILITY AND THE RISK OF DEVELOPING NEW DIABETES FOR THE HEALTHY ADULTS IN JAPAN
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OBJECTIVES: To evaluate the effect of A1C variability on the risk of developing new diabetes in healthy adults in Japan. METHODS: Population-based, retrospective cohort from 2005 to 2008 in Tokyo, Japan. In healthy adults not taking diabetes medication with and without 6.5 of Hba1c at baseline, we measured annually the serum Hba1c and calculated the annual visit to visit variability: RESULTS: At baseline, 14,764 people (49% female) with a mean age of 50 years old (SD: 12 years, range: 23 to 92), a mean fasting plasma glucose (FPG) level of 98.4 mg/dL (SD: 9.3 mg/dL) and a mean Hba1c level of 5.3 % (SD: 0.4 %) had annual check-ups over 4 years. Using the multivariate logistic regression, the A1C variability (odds ratio [OR]) and the correlation coefficient (r) of Hba1c level with FPG was strongly related to the development of diabetes. 22.2% of patients with unstable angina and 22% patients with ESRD. The results of two studies regarding Polish population indicate that 15.3% of patients with stable angina pectoris suffer from DM. The results of studies coming from European countries, which were identified by searching medical databases and Polish registries. Publications were selected in a specific order, to ensure that included data are the most representative for Polish population. Firstly, studies conducted in Polish settings were included and, if no reliable publications were found, European, non-European Caucasian and other (not specified) population were analyzed. Population based registries were considered as the most appropriate type of data. When no registry was available systematic reviews of observational studies were included. If systematic review was not available – data from clinical studies were taken into account. RESULTS: According to polish registries, DM was present in 28.9% of 2,683 matched pairs. Matched cohorts were compared using paired t-tests and nonparametric tests as appropriate. The effectiveness endpoints were changes in A1C (primary endpoint), weight, body mass index (BMI), blood pressure (BP), lipid levels, and hypoglycemia rates. RESULTS: The matched exenatide and glargine (n=1,156) cohorts achieved greater mean (± SD) reduction in A1C (0.66% ± [1.5] versus 0.41% ± [1.7], P<0.01), weight (2.6 [6.8] vs. -0.2 [-9.2] kg, P=0.01), BMI (0.9 [2.6] versus -0.1 [-2.7] kg/m², P<0.01), and systolic BP (1.8 [17] vs. -0.3 [-18] mmHg, P<0.01). More exenatide-treated patients reached the A1C goal of <7% (46% vs. 36%, P<0.01). There were no clinically significant differences in diastolic BP, lipid levels, and hypoglycemia rates between cohorts. CONCLUSIONS: Exenatide-treated patients experienced significantly greater reductions in A1C, weight, BMI, and systolic BP than the glargine cohort. These results demonstrated the clinical effectiveness of exenatide compared to glargine in a large, diverse, ‘real-world’ patient population treated in the ambulatory care setting.

Diabetes/Endocrine Disorders – Cost Studies

PDB21
BUDGET IMPACT ANALYSIS OF THE REIMBURSEMENT OF LONG-ACTING INSULIN ANALOGUES IN POLAND
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OBJECTIVES: According to HTA reports regarding long-acting insulin analogues (LAIA) these drugs should be reserved for use in selected diabetic patients only. In line with recent knowledge, LAIA in Poland are planned to be reimbursed in framework of therapeutic programme (LAIA-TP). This study assess the impact of this decision on public health-payers budget. METHODS: The analysis was performed using modelling technique, based on systematic review of LAIA, Polish epidemiological data and expert interviews. LAIA were compared. (A) LAIA not reimbursed. (B) LAIA reimbursed for patients with episodes of severe hypoglycemia (after 6 months reimbursement continued only in patients successfully treated). In each scenario annual costs of insulinotherapy, monitoring and tretament of hypoglicae-mia were estimated in 3-years time horizon. Model was run by having the current patient cohort progress through the model accompanied by the addition each year of a new cohort of eligible patients. Extreme scenario sensitivity analyses were performed. RESULTS: The expected number of diabetic patients eligible for LAIA would be 12,611 in the 1st year, and each year 661 “new” patients will meet inclu-sion criteria. Only 25% patients with type 1 and 30% patients with type 2 diabetes will be successfully treated with LAIA. The introduction of LAIA-TP is expected to increase public-payers expenditure in years 1st -3th by 12,168,582, 7,972,737 and 8,135,012 PLN, respectively (1 PLN=0.25 EUR, 2013). An increase in such cost would be associated with acquisition cost of LAIA and would be only partially compen-sated by lower costs of monitoring and treatment of hypoglicae-mia. Depending on assumptions about population and effectiveness of LAIA the additional expendi-tures of public payer varies between 11,295,941, 8,962,648 PLN, 7.219,765-9,627,449 PLN and 7,566,552-10,505,485 PLN in 1st, 2nd and 3rd year, respectively.
CONCLUSIONS: Budget impact analysis indicates that reimbursement of LAIA-TP seems to be affordable to the budget holder.

PDB22
BUDGET IMPACT ANALYSIS OF THE USE OF ASPART INSULIN DURING 'REAL-WORLD' CLINICAL OUTCOMES OF EXENATIDE BID COMPARED TO GLARGINE IN PATIENTS WITH TYPE 2 DIABETES
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OBJECTIVES: The safety and efficacy of exenatide BID (exenatide) compared to insulin glargine (glargine) has been studied in clinical trials and use of exenatide has been associated with reductions in A1C and weight. This study examined the clinical outcomes of exenatide versus glargine in patients with type 2 diabetes in a ‘real-world’ ambulatory care setting. METHODS: A retrospective analysis was conducted using the General Electric electronic medical record database to select exenatide (n=4,494) and glargine (n=5,424) cohorts. These cohorts were propensity-score matched to control for baseline demographic, clinical, and resource use variables (2,683 matched pairs). Matched cohorts were compared using paired t-tests and nonparametric tests as appropriate. The effectiveness endpoints were changes in A1C (primary endpoint), weight, body mass index (BMI), blood pressure (BP), lipid levels, and hypoglycemia rates. RESULTS: The matched exenatide and glargine (n=1,156) cohorts achieved greater mean (± SD) reduction in A1C (0.66% ± [1.5] versus 0.41% ± [1.7], P<0.01), weight (2.6 [6.8] vs. -0.2 [-9.2] kg, P=0.01), BMI (0.9 [2.6] versus -0.1 [-2.7] kg/m², P<0.01), and systolic BP (1.8 [17] vs. -0.3 [-18] mmHg, P<0.01). More exenatide-treated patients reached the A1C goal of <7% (46% vs. 36%, P<0.01). There were no clinically significant differences in diastolic BP, lipid levels, and hypoglycemia rates between cohorts. CONCLUSIONS: Exenatide-treated patients experienced significantly greater reductions in A1C, weight, BMI, and systolic BP than the glargine cohort. These results demonstrated the clinical effectiveness of exenatide compared to glargine in a large, diverse, ‘real-world’ patient population treated in the ambulatory care setting.