

without previous injection experience were more likely to use a support program. For 67% of patients using any program, the corresponding medication was the first injectable taken. The proportion who rated their program as extremely useful (6 or 7 on a 7-point scale) was 57% for BSS, 54% for VC, and 68% for LC. Overall, 49% reported using their program for 6 months or longer. Length of utilization was highest for LC with 31% reporting using the program for  $\geq 1$  yr. The program components most commonly used were educational materials (used by 75%), coupons (43%), telephonic support (31%), and medication reminders (8%). Use of educational materials was highest for LC, use of coupons was highest for VC, and use of telephonic support and reminders was highest for BSS. **CONCLUSIONS:** Although the minority of patients reported using these patient-support programs, those who did use them reported high levels of satisfaction and relatively long engagement.

## PDB126

## REAL LIFE TREATMENT OF DIABETES MELLITUS TYPE 2 PATIENTS: AN ANALYSIS BASED ON A LARGE SAMPLE OF 449,368 GERMAN PATIENTS

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**OBJECTIVES:** The aim of this claims-based data analysis was to describe the inpatient/outpatient care of German T2DM patients and to determine which subgroups could be differentiated in terms of the achieved T2DM-related treatment results, the underlying comorbidities, and the achieved comorbidity-related treatment results. **METHODS:** We included all T2DM patients insured by one large sickness fund in 2010/2011. We defined 12 different T2DM patient subgroups according to observed HbA<sub>1c</sub>, blood pressure, and Charlson Comorbidity Index (CCI). For each subgroup, available sociodemographic information, HbA<sub>1c</sub>, blood pressure, CCI, BMI, kidney status, and previous micro- and macrovascular events the patients experienced were reported. Furthermore, outpatient/inpatient as well as medication treatment was described. T2DM related events leading to acute hospitalisations were reported for all subgroups. **RESULTS:** We included 394,828 T2DM-patients in our analysis (age 73.10 years; CCI 6.86); for 228,703 patients detailed laboratory data as basis for subgroup classification were available. For 4.5% of the patients, a HbA<sub>1c</sub>>9% was observed. Across all patient subgroups, a total of 21,833 of the patients involved were affected by a T2DM-related event; the risk was 5.53% per patient year; 1.74% of the patients suffered from more than one event. Most frequent event types were hospitalisation with T2DM as primary diagnosis (2.39%), vascular interventions/stent implantations (1.92%), and ischaemic stroke (1.19%). There were significant differences between the observed subgroups in terms of T2DM-related event risk; belonging to a specific subgroup is an independent predictor of the event risk. **CONCLUSIONS:** Overall, our data indicate that the typically treated T2DM patient has a number of comorbidities and thus treatment focused solely on T2DM is neither possible nor clinically meaningful. Particularly those patients who reached HbA<sub>1c</sub> goals, but had also achieved relevant additional treatment goals reached low yearly T2DM event rates whereas subgroups failing to achieve one or several treatment goals are facing much higher event risks.

## PDB127

## TRENDS OF APPROVAL AND PRICES OF BRAND DIABETES MEDICATIONS

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**OBJECTIVES:** Diabetes mellitus (DM) is one of the diseases with the largest health care expenditures, with an estimated cost of \$245 billion in 2012. We assessed US Food and Drug Administration (FDA) approval trends and manufacturer listed prices at approval of diabetes medications. **METHODS:** Regulatory data were derived from the FDA website and average wholesaler price (AWP) per unit from the RedBook (Truven Health Analytics, Inc.). Descriptive statistical methods were used in the analysis. **RESULTS:** There were 104 medications approved for DM as of January 1, 2014. Among them, 53% were insulins and 47% oral antidiabetes drugs (OAD). The FDA designated 8 orphan indications for diabetes, but not orphan designations were approved to date. The number of insulin approvals was higher during the 1980's and the number of OAD approvals was higher between 2000 and 2009. The rate of market discontinuation was 75.0% for insulins and 18.4% for OAD. There were a total of 23 OADs with generic market competition. The mean time from new drug application approval to abbreviated new drug application approval was 15.4 years. Mean AWP unit prices were \$1.25 for insulins and \$0.30 for OADs in the 1980's, and increased to \$6.45 and \$12.73, respectively in the 2000's. From the 1980s to the 2000s, OAD manufacturer prices at approval increased by 42 times and insulin prices increased by 5 times. In comparison, the consumer price index increased 2.8 times during the same period. **CONCLUSIONS:** OAD products represented the largest percentage of new products approved for diabetes after 2000. In contrast, the number of insulin approvals decreased during the same period. There were not orphan approvals indicating the high prevalence of DM in the US. Manufacturer listed prices increased at higher pace than the inflation during the study period.

## PDB128

## INSULIN PUMPS FOR THE TREATMENT OF TYPE 1 DIABETES MELLITUS: WHY IS UPTAKE SO LOW IN THE UK?

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**OBJECTIVES:** NICE technology appraisal TA151 (Continuous subcutaneous insulin infusion [CSII] for the treatment of diabetes mellitus) was issued in July 2008, replacing TA57 from February 2003 and recommending uptake of CSII pumps in (1) adults with type 1 diabetes mellitus (T1DM) who fail to reduce HbA<sub>1c</sub> <8.5%, or disabling hypoglycaemia using multiple daily injections (MDI), (2) and children without requiring previous MDI-failure. CSII uptake in the UK rose to 4% between 2003–2008 and

to 6% between 2008–2013. It still lags behind NICE's 2008 benchmark of 12%, in addition to uptake in other Western countries. We aimed to understand why the UK has comparatively low pump uptake. **METHODS:** We performed a structured PubMed literature review using search terms "Continuous subcutaneous insulin infusion" AND glycaemi\* OR hypoglycaemi\* OR "costs and cost analysis[MeSH]", published after 01/01/2008. Captured articles were sifted; excluding irrelevant articles, or those not in English. Other relevant reports were captured by horizon scanning. **RESULTS:** Our search terms captured 113 articles. Reviewing reports meeting the inclusion criteria revealed that since 2008, additional studies contribute evidence supporting CSII efficacy in improving HbA<sub>1c</sub>, glycaemic variability and incidence of hypoglycaemia compared to MDI; in addition to being well-tolerated by patients. Recent cost-analyses suggest that CSII remains cost-effective, especially when increasing baseline HbA<sub>1c</sub>, hypoglycaemia avoidance, or pump life expectancy. Furthermore, there may be a low availability of specialised nurses, dietitians and other clinicians that NICE recommends are required to form part of a CSII-specialised multi-disciplinary team. **CONCLUSIONS:** It is surprising that given the amount of evidence supporting the efficacy, safety and cost-effectiveness of CSII, uptake of pumps by T1DM patients remains low in the UK. It is interesting that current evidence may be undermined by poor availability of clinical staff specialised in CSII, thus preventing new patients from effectively managing their condition.

## PDB129

## NEBIBE VAROL

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**OBJECTIVES:** To evaluate treatment patterns of Type 2 diabetes (T2DM) patients initiating glucagon-like peptide-1 receptor agonists (GLP-1) in Canada. **METHODS:** Adult T2DM patients initiating a GLP-1 between January 2010 and December 2011 were identified using the IMS retail pharmacy database (LRx). Initiation was termed 'index date'. Eligible patients were naive to GLP-1 class and had  $\geq 180$  days pre-index (with  $\geq 1$  oral anti-hyperglycemic agent used) and  $\geq 360$  days post-index of patient and data stability. Patients were followed through December 2012. Treatment patterns over the variable follow-up, and average daily dose of the index therapy while persistent were assessed. Outcomes were summarized overall and by GLP-1 therapy: exenatide twice-daily (exBID) or liraglutide (LIRA). **RESULTS:** 12,417 GLP-1 initiators, 242 exBID and 12,175 LIRA, were included, with mean (SD) follow-up of 14.9(1.5) and 20.6(4.8) months, respectively. Overall, approximately half were male (49.9%) with mean (SD) age of 57.2(9.9) years at index. 70.1% GLP-1 initiators were privately insured; 5.0% publicly covered and 21.4% were based on out-of-pocket payments. In the 180 day pre-index period, 33.7% of GLP-1 initiators used two concomitant anti-hyperglycemic agents, 27.9% used three, 19.7% used only one, and 8.4% used >3. The most frequent concomitant medications in the pre-index were biguanides (75%), sulfonylureas (43.9%), and DPP-IV inhibitors (24.7%). At index, 35.9% of GLP-1 initiators used one concomitant anti-hyperglycemic agent in addition to the initiated GLP-1, while 44.3% used  $\geq 2$ . The most frequent concomitant medication classes were biguanide (61.1%) and sulfonylurea (30.4%). Co-occurring cardiovascular medications (87.2% in the pre-index; 81.1% at index) were commonly used, as were lipid-lowering medications, specifically (72.6% in the pre-index; 62.9% at index). Over the variable-length follow-up, mean(SD) daily dose was 19.8(3.2) $\mu$ g for exBID, 1.58(0.14)mg for LIRA. **CONCLUSIONS:** Treatment patterns varied among GLP-1 patients in Canada. Longer-term data would be useful to further elucidate practice patterns.

## PDB130

## TREATMENT PATTERNS OF ANTI-VASCULAR ENDOTHELIAL GROWTH FACTOR (VEGF) AND LASER THERAPY AMONG PATIENTS WITH DIABETIC MACULAR EDEMA (DME)

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**OBJECTIVES:** 1) Compare demographic and clinical characteristics and treatment patterns of anti-vascular endothelial growth factor (VEGF) (bevacizumab, ranibizumab, pegaptanib) and laser therapies among diabetic macular edema (DME) patients; 2) Determine predictors of switching and anti-VEGF therapy initiation. **METHODS:** A retrospective cohort analysis was conducted with Texas Medicaid medical claims (1/1/08-12/31/12) for patients who were: 18- 63 years, continuously enrolled one year pre- and post-index, diagnosed with DME and treated with anti-VEGF or laser. Treatment patterns included treatment frequency and switching between anti-VEGF and laser. Logistic regression was used to predict switching and initiation of anti-VEGF while controlling for demographic (age, gender, race) and clinical characteristics (visual impairment, Charlson Comorbidity Index (CCI), number of unique prescriptions). **RESULTS:** DME patients (N=2158) were 54.7 $\pm$ 7.8 years, 62.7% female and 58.3% Hispanic. 9.7% were visually impaired, CCI mean score was 6.5 $\pm$ 3.2 and patients were on 2.6 $\pm$ 3.2 unique prescriptions. A higher (p=0.03) percentage of females were treated with laser (63.7%) compared to anti-VEGF (57.6%). Anti-VEGF users (1.9 $\pm$ 3.0) had fewer (p<0.0001) prescriptions compared to laser (2.7 $\pm$ 3.2). Laser was most commonly used (84.4%); however, anti-VEGF use increased from 12.6% in 2009 to 23.8% in 2011 (p<0.0001). Patients received 2.2 $\pm$ 1.4 laser surgeries compared to 2.4 $\pm$ 1.8 anti-VEGF injections. Switching from laser to anti-VEGF was 9.6%, while anti-VEGF to laser was 42.4%. Logistic regression showed that switchers were more likely to be Hispanic (OR=1.442;95%CI=1.053-1.975), male (OR=1.333;95%CI=1.043-1.703), have fewer prescriptions (OR=0.946;95%CI=0.907-0.986) and less likely to have no visual impairment (OR=0.620;95%CI=0.434-0.885). Anti-VEGF initiators were likely to be Hispanic (OR=1.402;95%CI=1.032-1.906), have fewer prescriptions (OR=0.909;95%CI=0.871-0.950) and initiate in 2011 vs. 2009 (OR=2.298;95%CI=1.722-3.065). **CONCLUSIONS:** Conclusions: Although anti-VEGF use is increasing, laser therapy is still more prevalent. Also, slightly over 40% of patients who initiated on anti-VEGF switched to laser after the first treatment. Additional research should be conducted to determine factors associated with this high rate of switching.