(year of marketing approval) of OADs. Using observations for 10 years and five regions, it was possible to estimate a multiple regression model explaining separately hospitalizations and hospital costs attributable to diabetes by regional fixed effects, "treated prevalence" and the average "vintage" of OADs. **RESULTS:** The results showed that the number of hospitalizations attributable to diabetes are proportional to the "treated prevalence", all else constant, but that the more recent the OADs used (higher "vintage"), the lower are hospital admissions (p=0.03) and hospital costs (p=0.007). According to the model, if the average "vintage" of OADs had increased by one year, the number of admissions would have had a 3.8% reduction (3965 less episodes in 2009) and hospital costs would have suffered a 5.3% reduction (about 11 M€ in 2009). **CONCLUSIONS:** The possible influence of other difficult to quantify factors notwithstanding, our analysis suggests that in the last decade the availability of new OADs in the Portuguese market may have played a key role in the reduction of hospital costs and in-patient admissions attributable to diabetes.

PDB47
EFFECTS OF PATIENT-REPORTED NON-SEVERE HYPOGLYCAEMIA ON HEALTH CARE RESOURCE USE AND WORK-TIME LOSS IN SEVEN EUROPEAN COUNTRIES

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OBJECTIVES: Limited data exist on the use of health care resources due to hypoglycaemia induced by antidiabetic treatment. This study investigated the occurrence of self-reported non-severe hypoglycaemic events (NSHE) in type 1 (T1) and insulin-treated type 2 (T2) diabetes patients and their impact on health care resource use. **METHODS:** Insulin-treated T1 and T2 patients from Austria, Denmark, Finland, The Netherlands, Norway, Sweden and Switzerland were invited, primarily via online panels, to complete four questionnaires at weekly intervals. Data were collected on patient demographics, occurrence of NSHE in the last seven days and hypoglycaemia-related resource use. NSHE was defined as an event with symptoms of hypoglycaemia, with or without blood glucose measurement (BGM), or low BGM without symptoms, which the patient could manage without assistance. **RESULTS:** In total, 3958 patients with diabetes entered the study (57% completing all four questionnaires). T1 and T2 patients experienced a mean of 1.7 and 0.5 events/pt-week. Overall employment rate was 48%. Following the last NSHE, the proportion of patients contacting a health care professional was 8% among T2 patients (Austria: 10%, Denmark: 7%, Finland: 10%, Norway: 6%, The Netherlands: 8%, Sweden: 6%, Switzerland: 14%) and 2% among T1 patients (Austria: 3%, Denmark: 1%, Finland: 3%, Norway: 2%, The Netherlands: 3%, Sweden: 1%, Switzerland: 5%). There was a mean increase in BG test use in the week following the last NSHE of 1.9 across countries (Austria: 2.6, Denmark: 1.3, Finland: 2.1, The Netherlands: 2.0, Norway: 1.8, Sweden: 1.5, Switzerland: 1.9). Among employed patients, loss of work-time after the last hypoglycaemic event was reported by 10% (Austria: 10%, Denmark: 9%, Finland: 17%, The Netherlands: 11%, Norway: 9%, Sweden: 12%, Switzerland: 6%). Between countries the average work-time loss among those losing work-time ranged from 1.3 to 6.7 hours. **CONCLUSIONS:** NSHE were associated with use of health care resources and work-time loss in the countries studied.

PDB48
HEALTH CARE RESOURCES UTILIZATION AND COSTS ASSOCIATED WITH THE MANAGEMENT OF PATIENTS WITH ACROMEGALY: AN ANALYSIS BASED ON THE RAMQ DATABASE

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OBJECTIVES: To estimate the health care resource utilization and costs associated with the management of patients with acromegaly in Québec. **METHODS:** A retrospective cohort study was conducted using data from the Quebec public health plan (RAMQ) for the period from January 2001 to June 2011. Patients with at least two diagnosis of acromegaly (ICD9=2530) reported by an endocrinologist or an internist were selected. Characteristics of the study population are described in terms of age, gender and co-morbidities. Health care resources utilization was estimated, in terms of medical/surgical services, hospitalization, emergency visits and medications. Costs of these resources were estimated annually over a three-year period from the time of diagnosis of acromegaly and from the time of specific intervention (transsphenoidal surgery (TSS) or medical treatment). **RESULTS:** A total of 655 patients had at least diagnosis of acromegaly on two occasions reported by an endocrinologist or an internist. Average age was 49.0(SD=19.1) and 55.4% were females. A pituitary adenoma was reported in 27.0% of patients. During the study period, TSS was performed for 20.3% of patients while 19,7% had a medical treatment. Medical therapy included bromocriptine (9.2%), cabergoline (7.6%), octreotide (7.2%), lanreotide (0.5%) and pegvisomant (0.3%). Annual costs for all patients were $7,203(SD=$12,706), $5,038(SD=9,545) and $5,266(SD=12,291) respectively for each of the three year following initial acromegaly diagnosis. For patients who had a TSS or a medical treatment, or a combination of these, total cost in the first year following the initial intervention varies from $9,925 to $17,813. The most frequent comorbidities were diabetes (47.6%) and hypertension (42.7%). Sleep apnea and carpal tunnel syndrome were reported in 11.1% and 5.3% of patients respectively Average annual costs of medications for the treatment of comorbidities were $1,454(SD=3,338). **CONCLUSIONS:** Results of this analysis of the RAMQ database illustrate the significant economic burden of acromegaly and of its comorbidities.

PDB49
COST AND HEALTH CARE RESOURCES UTILIZATION IN THE MANAGEMENT OF CUSHING'S DISEASE: AN ANALYSIS BASED ON THE RAMQ DATABASE

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OBJECTIVES: To estimate the health care resource utilization and costs associated with Cushing's disease (CD) in Québec. **METHODS:** A retrospective cohort study was conducted using data from the Quebec public health plan (RAMQ) from January 2001 to June 2011. Patients with at least two CD diagnoses (ICD9=2550) were initially selected. CD was further confirmed with at least 2 diagnoses of CD reported by an endocrinologist, or a diagnosis of pituitary adenoma, or a transsphenoidal surgery (TSS) or a bilateral adrenalectomy (BLA). Health care resources comprise medical/surgical services, hospitalization, emergency visits and medications. Costs of these resources were estimated annually over a three-year period from the time of diagnosis of CD and from the time of specific intervention (TSS, BLA or medical treatment). **RESULTS:** Of the 810 patients with two diagnoses of CD, 322 were considered confirmed cases of endogenous CD. The average age was 48.0yrs (SD=16.8) and 72.0% were females. During the study period, TSS and BLA were performed for 23% and 21.1% of patients respectively while 11.8% had a medical treatment to control hypercortisolism. Among these patients 5.9% had two interventions and 0.9% had the three interventions. Annual costs for all patients were $14,451, $5,737 and $5,679 respectively for each of the three year following initial CD diagnosis. For patients who had a TSS, or a BLA, or a medical treatment, or a combination of these, total cost in the first year following the initial intervention varied from $12,258 to $28,888. The most frequent comorbidities were diabetes (58.4%), hypertension (57.8%), and osteoporosis (51.2%). Patients had numerous comorbidities; 85.1% had 2 or more and 69.0% 3 or more. Average annual costs of medications for the treatment of comorbidities were $2,252 (SD=5,713). **CONCLUSIONS:** Results of this analysis of the RAMQ database illustrate the significant economic burden of CD and of its comorbidities.

PDB50
HEALTH CARE RESOURCE UTILIZATION IN THE MANAGEMENT OF CUSHING DISEASE: AN ANALYSIS FROM SOUTH-WESTERN ONTARIO

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OBJECTIVES: To examine the demographic and clinical characteristics in patients with Cushing's disease (CD) and to estimate the health care resource utilization associated in these patients in Ontario. **METHODS:** Retrospective analysis of resource use captured in the Southwestern Ontario Database from 2001 to June 2011. A total of 86 patients (72% females) were analyzed based on diagnosis, out of a total population of 523,718 patients. A matched control group (CG) (N=86) was also included from the general population. **RESULTS:** Age of patients at the time of diagnosis was 43±25.4 years (mean ± SD). Baseline co-morbidities (CM) included hypertension (67.4%), dyslipidemia (25%), diabetes (23.3%), renal calculi (17.4%), visual disturbance (20.9%), carpal tunnel syndrome (19.8%) and osteoporosis (11.6%). Distribution of co-morbidities was statistically significantly higher than general population (p-value <0.05); 27% had 2 CM and 35% had 3 or more CM. Baseline Urinary Free Cortisol (UFC) level was 207.7± 118.3 nmol/day (UFC ULN= 110 nmol/day). Primary treatment options included transsphenoidal surgery (TSS), bilateral adrenalectomy (BLA), radiosurgery and medical therapy, used in 79%, 6%, 2.3% and 12.7% of patients respectively. Secondary treatment was surgical in 37% of patients: consisting of repeat TSS in 21%, BLA in 10% and RS in 6%, while the majority received medical therapy (63%). Average length of stay for surgery was 6 days (SD=4) and 9 days (SD=7) for TSS and BLA respectively. Medical therapy, prescribed as monotherapy, included ketoconazole (38%), cabergoline (21%), bromocriptine (20%) and mitotane (15%). Health care provider interactions per year for CD post intervention compared to CG were: Emergency Room visit: 1.01 vs. 0.069; clinic visits: 4.86 vs. 1.89; specialist clinic visits: 5.57 vs. 0.92; and hospitalizations: 0.34 vs. 0.15. **CONCLUSIONS:** This retrospective analysis of patients diagnosed with Cushing's disease indicates that they require substantially higher resource use and experience a high burden of comorbidities.

PDB51
RESOURCE UTILIZATION IN THE MANAGEMENT OF ACROMEGALY: AN ANALYSIS FROM SOUTHWEST ONTARIO

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OBJECTIVES: To examine the demographic and clinical characteristics in patients with acromegaly and to estimate the health care resource utilization associated in these patients in Ontario. **METHODS:** Retrospective analysis of resource use captured in the Southwestern Ontario Database from 2001 to June 2011. A total of 131 patients (56% males) were analyzed based on diagnosis, out of a total population of 523,718 patients. A matched control group (CG) (N=131) was also included from the general population. **RESULTS:** Age of patients at the time of diagnosis was 35±25.3 years (mean ± SD). Primary treatment options included transsphenoidal surgery (TSS), radiosurgery and medical therapy, used in 38%, 6% and 56% respectively. Secondary treatment was surgical in 70% of patients: consisting of repeat TSS in 61% and RS in 9%, while 30% received medical therapy. Average length of stay for surgery was 8±8 days in first line TSS. Most frequent post operative complications (>50%) was metabolic-related (81%), gastrointestinal (62%) and fever (38%). Medical therapy, prescribed as monotherapy, included octreotide (47%), lanreotide (33%),

pegvisomant (13%) and bromocriptine (7%). Baseline co-morbidities (CM) included hypertension (66%), carpal tunnel syndrome (23%), osteoporosis (16%), dyslipidemia (12%), visual disturbance (12%), sleep apnea (2%), myocardial infarction (2%) and renal calculi (2%). Distribution of co-morbidities was statistically significantly higher than general population (p-value <0.05); specifically those with 1 CM (41%) or 3 CM (19%) or more. Longitudinal assessment of co-morbidities reported no statistically significant difference prior and post therapy. **CONCLUSIONS:** This retrospective analysis of patients diagnosed with acromegaly indicates that they require substantially higher resource use and experience a high burden of comorbidities.

DIABETES/ENDOCRINE DISORDERS - Patient-Reported Outcomes & Patient Preference Studies

PDB52
ADHERENCE: A REAL WORLD RETROSPECTIVE DATABASE STUDY AMONG TYPE 2 DIABETES PATIENTS TREATED WITH LIRAGLUTIDE OR EXENATIDE

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OBJECTIVES: An important factor to take into account when evaluating the effectiveness of a drug is adherence. Adherence describes the degree to which a patient correctly follows medical advice. The objective of this study was to evaluate the factors that determine adherence of adult patients with type 2 diabetes treated with once-daily injectable liraglutide 1.8mg or twice-daily injectable exenatide 10μg. **METHODS:** A retrospective study was conducted employing US data from the IMS PharMetrics claims database. The index period ranged from January 2010 to December 2010 and patients needed to be continuously enrolled 12 months before and after the index date. Patients were treatment naïve to liraglutide and exenatide but may not have been insulin-naïve as prior insulin use was not part of the patient selection exclusion criteria, which may have impacted the outcomes as a limitation of the study. Adherence was measured by continuous Medication Possession Ratio (MPR) as well as a categorical response using MPR (MPR≥80%=high adherence and MPR<80%=low adherence). The determinants of adherence were estimated using multivariable models and bivariate testing was conducted for selection of the possible predictors. Covariates were then included and a stepwise model-building approach was used. **RESULTS:** Data from 3623 patients (2036 liraglutide 1.8mg and 1587 exenatide 10μg) were used in the analyses. When adjusting for confounding effects, patients treated with exenatide 10μg were approximately 11% (p<.0001) less adherent than patients treated with liraglutide 1.8mg assessed by the continuous MPR measure. The odds ratio (OR) for achieving a high categorical MPR for liraglutide 1.8mg compared to exenatide 10μg was 1.33 in favor of liraglutide 1.8mg (p<.0001). Variables found to impact the level of adherence were age, gender, the geographic region, treatment, and percentage co-payment from the claimant. **CONCLUSIONS:** The analysis showed that once-daily liraglutide 1.8mg is associated with better adherence than twice-daily exenatide 10μg.

PDB53
PRELIMINARY RESULTS OF A MULTICENTER OBSERVATIONAL STUDY OF TREATMENT COMPLIANCE WITH FREE-COMBINATION VERSUS FIXED COMBINATION TREATMENT IN TYPE II DIABETES MELLITUS PATIENTS IN GREECE (LESS STUDY)

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OBJECTIVES: To assess the differences in the compliance of Greek patients suffering from Type 2 diabetes mellitus who receive free combination therapy of metformin and vildagliptin compared to the diabetic patients who receive fixed combination therapy of metformin/vildagliptin. **METHODS:** Eight hundred adult patients inadequately controlled on twice daily 850mg metformin monotherapy who were recently added vildagliptin treatment as add on to metformin (fixed dose combination or free combination) were enrolled in the study. The observation period was 6 months. Upon treatment initiation each patient received a diary, in which they had to record their treatment on a daily basis. The diary then was returned to the physician at the final visit. Additionally, at baseline and at the last visit of the study, patients were asked to complete a questionnaire related to their compliance of their indicated treatment. Patients were defined as compliant when they hadn't missed any drug dose, received the correct dosage of the medication and did not interrupt their treatment. **RESULTS:** The preliminary results the overall study sample 63% were considered to be compliant. In the between groups analysis, it was found that 56% of patients receiving free combination were compliant with their treatment compared to a substantially higher 68% of compliant patients in the fixed combination group (p<0,005). Odds Ratio was equal to 1,647, suggesting that patients receiving free combination were 1.647 times more likely not to comply with their treatment than the patients on fixed combination. A statistically significant reduction in Hb1Ac was observed in both groups between the first and last visit (p<0,001) but not any difference between two groups, which is attributed to the short follow-up period. **CONCLUSIONS:** Patients on fixed dose combination treatment for Type II Diabetes are more compliant than patients on free dose combinations. Improved compliance has been shown to improve disease management, which can prevent expensive complications.

PDB54
SYSTEMATIC LITERATURE REVIEW OF UTILITY VALUES ASSOCIATED WITH TYPE 2 DIABETES-RELATED COMPLICATIONS

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OBJECTIVES: Cost-utility analysis of type 2 diabetes mellitus (T2DM) interventions requires the estimation of utility values. To increase the robustness of such estimates in line with the National Institute for Health and Clinical Excellence (NICE) requirements a systematic literature review of utility values associated with T2DM-related complications was performed. **METHODS:** The review was performed according to NICE methodology recommendations using Medline, Embase, EconLIT and the NHS Economic Evaluation Database in May 2012. Health utilities selected were based on the NICE reference case, including a preference for EQ-5D data and UK population. Landmark study articles reporting multiple utility values were favoured. **RESULTS:** A total of 16,578 records were identified. 61 full text articles were included in the qualitative synthesis. T2DM without complication values ranged from 0.690 to 0.970. The proposed utility set primarily consisted of utility values extracted from Clarke 2002 (T2DM without complication: 0.785, myocardial infarction:-0.055, angina:-0.090, heart failure: -0.108, stroke: -0.164, severe vision loss: -0.074, amputation: -0.28) and Bagust 2005 (peripheral vascular disease: -0.061, protenuria: -0.048, neuropathy: -0.084, foot ulcer: -0.170 and overweight: -0.0061 per BMI unit above 25 kg/m2). These values were supplemented by Wasserfallen 2004 (haemodialysis: 0.621, peritoneal dialysis: 0.581); Kiberd and Jidal 1995 (renal transplant: 0.762); Fenwick (mild non-proliferative diabetic retinopathy or macular oedema: 0.760, vision threatening diabetic retinopathy: 0.730) as well as Currie 2006 (major hypoglycaemia: -0.270, minor hypoglycaemia: -0.070). Limitations included the partial lack of studies in a diabetic- or UK-specific population, the variability in reporting media, mean or values adjusted for confounding factors. **CONCLUSIONS:** This set of values should improve the robustness of T2DM modelling outcomes in line with NICE requirements. Future research could focus on eliciting a coherent set of values for T2DM-related complications in line with the NICE reference case and to define the variance around the utility value point estimates.

PDB55
THE ADAPTATION OF THE INJECTION PEN ASSESSMENT QUESTIONNAIRE FOR USE IN EUROPE – VALIDATION RESULTS FROM A LARGE MULTICENTER STUDY OF RECOMBINANT HUMAN GROWTH HORMONE TREATMENT NAÏVE CHILDREN AND ADULTS

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OBJECTIVES: To examine the reliability and validity of the Injection Pen Assessment Questionnaire (IPAQ) in a European population. **METHODS:** The IPAQ is a 29-item measure of objective and comparative ease of use and preference for recombinant human growth hormone (rhGH) injection devices based on content elicited from focus groups and one-on-one interviews of device users. The IPAQ was included in a Phase 3, open-label, multicenter trial in 136 experienced rhGH subjects (parent-child dyads) in the United States to test the ease of use and preference for a new Genotropin® disposable pen (NCT00965484). IPAQ content was adapted for use in adults and translated into seven languages. Data from a Phase 3, open-label, multicenter, crossover study (NCT01112865; N=120) was used to evaluate the psychometric properties of the IPAQ in a mixed sample of dyadic pairs, adult subjects and caregivers of pediatric subjects. Analyses were conducted by group and total sample. **RESULTS:** Confirmatory factor analysis provided evidence for a second order factor solution for four subscales and a total IPAQ score; and supported the conceptual framework developed from previous qualitative and quantitative research. Although IPAQ subscales did not consistently meet acceptable internal consistency reliability for some group level comparisons, the total IPAQ score showed high internal consistency for both pens (Cronbach's alpha = 0.77 – 0.86). In general, the construct validation (predictive validity) findings were consistent across pens and across subject groups and generally consistent with those from the US trial. **CONCLUSIONS:** The IPAQ total score for ease of use demonstrated good internal consistency reliability and good construct validity in measuring ease of use with injection pens to administer rhGH. Findings from this research are consistent with those from the US-based study, supporting the usefulness of the IPAQ total score in evaluating ease of use and preference for injection pens in clinical trials and in practice.

PDB56
DEVELOPMENT AND VALIDATION OF PATIENT REPORTED ENDPOINTS FOR T2DM

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OBJECTIVES: There are no existing patient reported outcome (PRO) measures in Type 2 Diabetes Mellitus (T2DM) developed in accordance with FDA Guidance on PROs. The objective of this study was to develop and validate a T2DM-specific PRO measure examining hypoglycemic symptoms (HS), weight neutrality (WN), medication tolerability (MT), and medication compliance (MC). **METHODS:** The Diabetes-Management and Impact Questionnaire (D-MIQ) and the Diabetes-Assessment of Blood Sugar Questionnaire (D-ABS) were developed in three phases: concept elicitation (CE; n=20), item generation, and cognitive interviews (CIs; n=20). The D-ABS was finalized as a 36-item PRO assessing HS with a yes/no response scale measuring symptom frequency and an 11-point numeric response scale measuring symptom severity. The D-MIQ was finalized as an 18-item PRO measuring impacts of HS, WN, MT, and MC, with four- and five-point Likert-type response scales and a yes/no scale. Following content validation, a stand-alone observational study was conducted in 100 subjects to assess the psychometric properties of the D-MIQ and D-ABS. **RESULTS:** Subjects had a mean age of 57.4 (SD 12.6) years (52% female, 60% white). All items on the D-ABS and D-MIQ showed good convergent validity with