

and 14/12% (N/D) contacted a health care professional. In the week after an event, respondents added an average of 2.8/3.6 (N/D) blood glucose tests to an average of 18.8/17.4 (N/D) tests in a normal week. Nocturnal events had a high impact on sleep quality (46% of respondents) and social life (24%), and 84% of respondents felt tired and/or fatigued the next day. In the daytime survey, about 26% reported the event highly impacted daily activities (outside of work). Also, 40/18% (N/D) of respondents indicated that the event had a high impact on their fear of hypoglycaemia. The majority ascribed hypoglycaemia to stress (50%/58% [N/D]) or irregular/insufficient food intake (50%/40% [N/D]). **CONCLUSIONS:** Both nocturnal and daytime hypoglycaemic events had an impact on patients' use of health care system, quality of life and daily productivity.

PDB102

CLINICAL SIGNIFICANCE OF CHANGE IN THE QUALITY OF LIFE-ASSESSMENT OF GROWTH HORMONE DEFICIENCY IN ADULTS (QOL-AGHDA) SCORE IN ADULT GROWTH HORMONE DEFICIENCY (AGHD)

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OBJECTIVES: To investigate the clinical significance of change in QoL-AGHDA score after 1 year of growth hormone (GH) replacement. **METHODS:** Observational data were obtained from KIMS (Pfizer International Metabolic Database). Minimal important differences (MID) for the QoL-AGHDA score and its five domains (memory and concentration, tenseness, tiredness, self-confidence, and social isolation) were calculated using an anchor-based approach with a rating of patient-perceived treatment benefit and patient-reported change in need for assistance. Perception of treatment benefit was measured using the KIMS Patient Life Situation Form (PLSF), a 5-point ordinal assessment of change (much improved, a little improved, no change, a little worse, much worse). The effect of baseline (BL) scores on MID was analysed using the QoL-AGHDA thresholds included in the New Zealand (≥ 16) and England (≥ 11) reimbursement criteria. **RESULTS:** Data from 1404 patients (52% female, 96% Caucasian, mean age [SD] of 45 [14] years) were included in the analysis. Mean GH dose [SD] was 0.20 [0.14] mg/day at BL and 0.32 [0.16] mg/day during Year 1. The Spearman correlation between change in QoL-AGHDA score and perception of treatment benefit was moderately positive (0.45; $p < 0.01$). The correlation was stronger for females and for patients with more impaired (higher) BL QoL-AGHDA scores. Using the anchor-based approach with patient-perceived treatment benefit, the MID for the QoL-AGHDA score was -4.61 at Year 1. Self-confidence was most sensitive and tenseness least sensitive of the domains in predicting patient-perceived treatment benefit. Patients requiring assistance at BL and not at Year 1 experienced the largest mean improvement in QoL-AGHDA score. **CONCLUSIONS:** Several national reimbursement authorities currently include the QoL-AGHDA score in eligibility criteria for access to reimbursed GH replacement. This is the first study to calculate the MID for the QoL-AGHDA score. Findings indicate that change in QoL-AGHDA score is positively correlated with patient-perceived treatment benefit.

PDB103

THE IMPACT OF DAYTIME AND NOCTURNAL NON-SEVERE HYPOLYCAEMIC EVENTS ON PEOPLE WITH DIABETES IN BRAZIL

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OBJECTIVES: This study examined the effects of nocturnal and daytime non-severe hypoglycaemic events on utilisation of health care services and patient quality of life in Brazil. **METHODS:** People with diabetes from six different countries who had experienced a non-severe hypoglycaemic event in the past 4 weeks were asked to take part in a nocturnal and/or daytime hypoglycaemia survey. In the Brazilian subgroup, 86 people responded (50 respondents per survey). The surveys were conducted either face to face or online; hypoglycaemic events were self-reported. **RESULTS:** In the Brazilian cohort (nocturnal [N]/daytime [D] survey, respectively), 80% (N)/76% (D) had type 2 diabetes, 46%/38% (N/D) were male, mean age was 41(N)/40(D) years and mean weight was 82.4 kg(N)/81.8 kg (D). Participants received treatment with insulin (53%/70% [N/D]), oral medication (61%/60% [N/D]), GLP-1 (0%/8% [N/D]) and/or diet and exercise (32%/45% [N/D]). Approximately a quarter of respondents (26%/22% [N/D]) reported that they generally experienced a hypoglycaemic episode at least once a week. After the non-severe nocturnal (N)/daytime (D) hypoglycaemic event, 29% and 53% (N/D) decreased their insulin dose and 38% and 50%, respectively, contacted a health care professional. Participants used on average 13.0 or 11.5 (N/D) extra blood glucose tests the following week and 56%/32% (N/D) of the surveyed reported a high level of fear of a hypoglycaemic event. Among the 44/43 (N/D) respondents who worked for pay, 48%/35% (N/D) went to work late or left early; 23%/9% (N/D) missed ≥ 1 full days due to the non-severe event and 55%/26% (N/D) said that the event highly impacted upon their productivity at work. **CONCLUSIONS:** In Brazil, nocturnal and daytime non-severe hypoglycaemic events severely impact upon patients' quality of life and work productivity, with half of patients surveyed decreasing their insulin dose and/or contacting their health care provider after a non-severe event.

DIABETES/ENDOCRINE DISORDERS – Health Care Use & Policy Studies

PDB105

HEALTH ECONOMICS ASSESSMENT OF THE CNAMTS SOPHIA DIABETIC PATIENT SUPPORT PROGRAMME: RESULTS OF THE FIRST 4 YEARS

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OBJECTIVES: Since 2008, the Caisse Nationale d'Assurance Maladie des Travailleurs Salariés has set up a diabetic patient support programme in ten pilot departments in France. In addition to written advice, programme members also have access to telephone support from health education nurses. In 2010, the sophia programme was extended to another nine departments and, at the beginning of 2013, it was generalized to all French departments. The present study evaluated the health economics impact of the programme after a follow-up of 3 years. This analysis follows a preliminary assessment that demonstrated positive results after 1 year. **METHODS:** The variation of various health care use indicators as well as outpatient and inpatient costs was compared between three cohorts: members of pilot departments, non-members, and a control group of diabetic patients living in departments in which sophia was not available. Results are adjusted for between-group differences observed at the beginning of the programme. **RESULTS:** Adjusted analysis showed that, after matching for all other characteristics, compliance with recommended examinations improved to a much greater extent among programme members than among control subjects and non-members. Although all health care costs continued to increase in each cohort, outpatient and inpatient expenditure was €226 lower for programme members than for controls for the period 2009–2011: -€54 for outpatient care and -€172 for inpatient care. Although the outpatient expenditure of programme members was higher (+€40) for outpatient visits and medical procedures, their paramedical expenditure was lower (-€89). Hospitalization rates for diabetes were significantly lower among members than among controls. **CONCLUSIONS:** These results confirm the significant impact of the sophia programme on compliance with clinical practice guidelines in diabetology, hospitalization rates, and the 3-year growth of outpatient and inpatient costs. An assessment of the impact of the sophia programme on clinical parameters will be conducted in the near future.

PDB106

CONSISTENCY OF CURRENT TYPE 2 DIABETES (T2DM) TREATMENT PATTERNS IN GENERAL PRACTICE VERSUS THE 2013 FRENCH HAS T2DM GUIDELINES: A TRANSVERSAL STUDY BASED ON THE FRENCH IMS LIFELINK™ PROSPECTIVE DIABETES COHORT

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OBJECTIVES: To evaluate the consistency of T2DM management by French GPs in 2012 versus 2013 HAS guidelines that recommend modulating glycaemic objectives depending on patient's profile. To assess current treatment need for T2DM patients. **METHODS:** A transversal study, based on the IMS LifeLink™ prospective Diabetes Cohort linked to Electronic Medical Records database (Disease Analyzer) was used to investigate patients' profiles (age, disease history and complications, renal impairment, cardiovascular events, co-morbidities), HbA1c, hypoglycaemic risk, self monitoring of blood glucose (SMBG), and BMI evolution, linked to the current treatment. **RESULTS:** A total of 6680 T2DM patients (56% men) were included in the 2012 study cohort. The mean age was 66.6 years (25% of patients above 75 years); 19% had moderate to severe renal impairment and 56% had cardiovascular history. The new HAS guidelines split patients into several categories with associated HbA1c objectives varying from 6.5% to 9% based on age, frailty, diabetes history, and co-morbidities. 4%, 35%, 43%, and 18% of diabetic patients were eligible for the 6.5%, 7%, 8%, and 9% HbA1c objectives respectively. It appears that 55% of the diabetic population were at risk of hypoglycaemia, age and long diabetes history being the major risk factors. Given the modulation of glycaemic objectives more patients reached the new HbA1c objectives (74% of patients) vs. previous guidelines (about 55%). In this representative cohort, SU were prescribed with no dosage adjustment to all patients and even more frequently to patients at risk of hypoglycaemia (60.6%) while DDP4i were prescribed to "healthy patients" mostly not at risk of hypoglycaemia (51.5%). **CONCLUSIONS:** A minority of T2DM patients (39%) are eligible for an HbA1c objective of 7% or below, highlighting their frailty. This survey also shows that more patients are reaching their HbA1c target. However many of them are receiving treatments they should not due to high risk of hypoglycaemia.

PDB107

THE IMPACT OF MEMORY PROBLEMS ON DIABETES TREATMENT IN GERMANY

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OBJECTIVES: The impact of memory problems (MPs) on patient functioning, well-being and diabetes management is not well understood. This study examines these impacts in Germany and compares findings to data from US, UK, Canada and China. **METHODS:** A 5 country web-based survey was conducted. MPs were defined as: unintentionally forgetting to take insulin (UF), questioning if insulin had been taken (QT), or questioning amount of dose (QD). **RESULTS:** A total of 350 German respondents (60.0% Type 1) completed the survey, 61.1% male, mean age of 39.5 (± 13.3) and mean age of diabetes onset 30.2 (± 12.6). The prevalence of MPs in the past month was: 74.0% UF, 82.0% QT and 68.3% QD. MPs occurred most frequently when waking in the morning or when relaxing. Between 27.9% (UF) – 48.3% (QD) of respondents skipped their insulin dose and waited for next scheduled dose when experiencing a MP. Patients experiencing MPs required between 2.0 (QT)–8.7 (UF) hours, on average, to return to normal blood glucose range, conducted between 1.2 (QT)–4.4 (UF) extra BG monitoring tests, reported a moderate negative impact on their physical and emotional functioning, work absenteeism or reduced ability to function optimally when at work and between 3.6% (QT) and 13.8% (QD) visited/contacted their health care provider due to MPs. Compared to the total sample (N=1404), German respondents were more likely to report that their diabetes was very well/well controlled and that they were very/extremely confident in knowing what to do when they had an MP compared to respondents and were less likely than patients in other countries to have contact with a physician or other health care professional following a MP. **CONCLUSIONS:** These findings suggest that MPs

carry financial burden, impact patients' daily functioning and well-being and may be serious obstacles to optimal diabetes control. This burden may be some lower in Germany than other countries.

PDB108

TREATMENT PATTERNS AND HEALTH CARE RESOURCE UTILIZATION OF PATIENTS WITH ACROMEGALY IN THE UNITED STATES

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OBJECTIVES: To examine patient characteristics, treatment patterns, and health care resource utilization of patients with acromegaly in the US. **METHODS:** Using a large US claims database, adult individuals with commercial insurance newly diagnosed with acromegaly (ICD-9-CM: 253.0) between 07/01/2007 and 12/31/2010 were identified (the first observed diagnosis was the index date). Patients were required to have 6-month pre-index and 12-month post-index continuous enrollment. Descriptive analysis was performed to describe demographic and clinical characteristics, treatment patterns of acromegaly, and health care resource utilization during the post-index period. Similar analysis was conducted for Medicare-eligible patients with supplemental private insurance. **RESULTS:** This study included 930 commercially-insured patients (mean age: 47.2 years; 52.0% female) and 104 Medicare-eligible patients (mean age: 72.8 years; 36.5% female) with acromegaly. For the commercial population, of the comorbidities evaluated, hypertension (38.2%), diabetes (25.9%), and arthropathy/arthralgia/synovitis (23.7%) had the highest prevalence. More than half of the patients (57.3%) received no treatment; 21.7% received tumor resection surgery and 21.0% received medical therapy as the first-line treatment. During the 12-month post-index period, one-third had inpatient hospitalization and 23.2% had emergency room visit; the mean physician office visit was 17.1. For the Medicare population, hypertension (67.3%), diabetes (36.5%), and arthropathy/arthralgia/synovitis (29.8%) were most prevalent comorbidities. About two-thirds (63.5%) received no treatment; 8.7% received tumor resection surgery and 27.9% received medical therapy as the first-line treatment. More than one-third (34.6%) had inpatient hospitalization and 26.9% had emergency room visit during the 12-month post-index period; the mean physician office visit was 21.1. **CONCLUSIONS:** Our findings suggest high unmet needs in the population with more than half of patients with acromegaly being untreated. Efforts should be made to understand this untreated population to provide better care. Future research should investigate different treatment options as well as their impact on health care costs and health care resource utilization.

PDB109

UK QUALITY OUTCOMES FRAMEWORK (QOF) THRESHOLDS AND LONGITUDINAL HBA1C LEVELS AMONG PATIENTS WITH TYPE II DIABETES - A LONGITUDINAL STUDY USING THE CLINICAL PRACTICE RESEARCH DATALINK (CPRD)

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OBJECTIVES: HbA1c concentrations predict the risk of complications in patients with type 2 diabetes mellitus (T2DM). This study assessed temporal trends in elevated HbA1c levels in the UK primary care setting. **METHODS:** T2DM was identified by medical diagnosis, prescribing, elevated blood glucose and/or prescribing of monitoring devices. Patients had ≥ 12 months of CPRD history, with data available for the entire year of observation. T2DM patients prescribed insulin were excluded. Mean HbA1c levels and proportion of patients with elevated HbA1c were assessed across six years (01/04/2006-31/03/2012). Elevated HbA1c was defined according to the UK Quality and Outcomes Framework (QOF) threshold: $>7.5\%$ for all years except 2009/2010 ($>7.0\%$). Estimates were stratified by age-band, gender, T2DM-status and treatment categories. **RESULTS:** Mean HbA1c levels among 176,428 patients were relatively stable and below threshold across the study period (2006/2007: 7.05%; 2011/2012: 7.16%), with the exception of 2009/2010 (7.09%). Nonetheless, $>20\%$ of patients had a record of elevated HbA1c in each year (36.7% in 2009/2010). Elevations were more common among males than females (20%-25.0% vs. 18%-20%) and among patients 40-59 years (27.2%-33.7%) vs. those ≥ 60 years (15.9%-23.3%). Although elevations were similar among prevalent (20%-23%) and incident-T2DM (22%-23%), prevalent-T2DM showed an increasing trend in the proportions with an elevation over time, whilst incident-T2DM showed a decreasing trend. The proportion with elevated HbA1c varied by treatment: diet and exercise 4.8%-6.1%; monotherapy 24%; dual therapy 32.7%-38.0%, and; triple therapy 42%-50%. Over 80% of patients with elevated HbA1c were overweight or obese, $>20\%$ had a 10-year Framingham Risk score $>20\%$ (patients without existing CVD) and 17%-21% of patients had history of chronic renal failure. **CONCLUSIONS:** Although mean HbA1c concentrations were below target (apart from 2009/2010), elevated HbA1c was present in $>20\%$ patients across all years. Further efforts are needed to help patients to achieve adequate glycaemic control.

PDB110

SELF-MONITORING OF BLOOD GLUCOSE WITH INSULIN ANALOGUES: NICE TO HAVE OR NEED TO HAVE? ANALYSIS OF PHASE III REGISTRATION TRIALS AND EUROPEAN PUBLIC ASSESSMENT REPORTS OF INSULIN ANALOGUES

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OBJECTIVES: Registration trials' purpose is to show safety and efficacy of insulin therapy. They are the basis of subsequent insulin reimbursement decisions. Insulin dosing is typically individualized: a safe and efficacious insulin therapy requires upfront dose finding and regular dose adjustments. These adjustments are based on data from Self-Monitoring of Blood Glucose (SMBG). However, some countries reimburse insulin analogues, but not blood glucose test strips. This analysis investigates the use of SMBG in Phase III registration trials of selected insulin analogues and if consequently the European Public Assessment Reports (EPARs) recommend the use of SMBG as part of the insulin therapy. **METHODS:** Systematic search and

analysis of phase III registration trials (full-publication if available, and Clinical Trial report/study Synopsis) and EPARs of commonly used short-acting (Insulin Aspart and Insulin Glulisine) and pre-mix (Biphasic Insulin Aspart) insulin analogues. **RESULTS:** Therapy adjustments based on SMBG data were documented in 5/24 Insulin Aspart-, 3/18 Insulin Glulisine- and 4/15 Biphasic Insulin Aspart phase III registration trials. The EPARs of all three insulin analogues recommend the use of SMBG to adjust the insulin doses, repeatedly and throughout all sections in EPAR. **CONCLUSIONS:** Overall, in 12/57 phase III registration trials the dose of insulin analogues was regularly adjusted based on SMBG data, and the EPARs of all insulin analogues explicitly recommend the use of SMBG to adjust the insulin doses. Therefore, the demonstrated safety and efficacy of these insulin analogues are the result of a complex intervention including insulin analogues, their dose adjustments based on SMBG data as well as training rather than the insulin analogues alone. This is not consequently reflected in reimbursement schemes, in particular in emerging countries. Full study reports were not available for further analysis. These potentially would have provided deeper insights on how SMBG was used in the remaining 45/57 trials.

PDB111

DIFFERENT INJECTION FREQUENCIES OF BASAL INSULINS IN TYPE 2 DIABETES PATIENTS UNDER REAL-LIFE CONDITIONS: A RETROSPECTIVE DATABASE ANALYSIS

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OBJECTIVES: Little is known about routine use of basal insulins (Glargine, Detemir, NPH) in primary care patients with type 2 diabetes. The aim was to compare injection frequencies of basal insulins in type 2 diabetes (T2D) in primary care practices, both for basal-supported oral (BOT) and basal-bolus (ICT) treatment regimens. **METHODS:** Primary care data from 4,503 Glargine (BOT/ICT: 2,247/1,964), 1,373 Detemir (490/800), and 4,072 NPH-insulin (1,331/2,425) users were retrospectively analysed (05/2009-04/2012). The Disease Analyzer database (IMS HEALTH) assembles drug prescriptions, diagnoses, basic medical and demographic data obtained from the practice computer system of general practitioners and specialists throughout Germany. The Charlson Comorbidity Index was used as generic marker of comorbidity. Logistic regression (>1 daily injection) and propensity scores were used to adjust for various confounders (age, sex, type of physician, dosage, BMI, HbA1c). **RESULTS:** Overall, more than one daily injections were observed in 7.5% of Glargine users (BOT: 6.2%, ICT: 9.0%), which was lower than for Detemir (overall: 25.4%; BOT: 22.0%, ICT: 27.4%) and NPH-insulin (25.4%; BOT: 23.9%, ICT: 27.2%) (all $p < 0.001$). The adjusted odds of having more than one injection was lower for Glargine compared to Detemir (OR: 95% CI: 0.26; 0.22-0.32) and NPH-insulin (0.20; 0.17-0.23). Similar results were found for BOT (Glargine vs. Detemir: 0.23; 0.17-0.32; Glargine vs. NPH-insulin: 0.16; 0.13-0.21) and for ICT (Glargine vs. Detemir: 0.27; 0.21-0.35; Glargine vs. NPH-insulin: 0.22; 0.18-0.27). Finally, after matching the groups for the propensity score, the odds for more than one daily injection was also significantly reduced in the Glargine group both compared to Detemir (OR: 95% CI: 0.30; 0.24-0.37) and NPH insulin (0.25; 0.22-0.29). **CONCLUSIONS:** Glargine is associated with significant lower injection frequencies than other basal insulins. These findings might impact treatment satisfaction and as a consequence quality of life, persistence and economic aspects of diabetes treatment.

PDB112

ORAL HYPOGLYCAEMIC MEDICINE (OHM) INITIATION IN NEWLY TREATED TYPE 2 DIABETES MELLITUS (T2DM) IN IRELAND: AN ANALYSIS OF TREATMENT INTENSIFICATION AND SWITCHING PATTERNS

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OBJECTIVES: To examine treatment intensification and switching patterns of individuals with T2DM initiating OHM. The results are compared to international guidelines issued in 2009. **METHODS:** Data were analysed using a population-based pharmacy claims database from January 2008 to November 2012. Incident users of OHM were identified for 2008-2009 as not having received OHM in the previous 12 months. Patients dispensed insulin, $>one$ OHM, or <16 years were excluded from the study. Patients were followed until Nov-2012. Treatment intensification was defined as receiving an additional one, or two hypoglycaemic medicines (double or triple-therapy respectively). Treatment switching was defined as OHM monotherapy discontinuation with initiation on alternative monotherapy. **RESULTS:** A total of 24,869 patients were included in the study. Most were initiated on metformin (76.4%) or sulphonylureas (21.6%). Treatment intensification: 25.8% of patients initiated on metformin progressed to double-therapy. Sulphonylureas (61.5%), DPP-4 inhibitors (23.9%) and GLP-1 agonists (6.2%) were the most frequently prescribed add-on treatment (median time to add-on OHM=424days). Of those initiated on sulphonylureas 32.4% progressed to double-therapy; metformin (78.4%), DPP-4 inhibitors (9.3%) and long-acting insulin (5%) were the most frequently prescribed (median time to add-on=295days). 14.3% of patients on double-therapy progressed to triple-therapy (median time to add-on=434days). 26.6% of patients did not receive the recommended double-therapy and 64.3% received agents in their triple-therapy that were not recommended. Treatment Switching: Overall 7.1% switched medication. The most frequent switches were metformin to sulphonylureas (46.5%, median time to switch=226days), sulphonylureas to metformin (22.5%, median time to switch=330days) and metformin to DPP-4 inhibitors (6.9%, median time to switch=577days). Initial OHM was significantly associated with time to switch ($p < .0001$). **CONCLUSIONS:** Initial drug treatment followed guidelines. However, evidence-based practice was not closely followed for treatment intensification suggesting prescribers may be unaware of treatment guidelines. This data may be useful for assessing the potential place in therapy, and cost-effectiveness of new hypoglycaemic medicines.