inclusion of the symptoms. The heterogeneity in defining hypoglycaemia makes it difficult to compare the safety of interventions for their drug-induced hypoglycaemia.

**DIABETES/ENDOCRINE DISORDERS – Cost Studies**

**PDB24**

**BUDGET IMPACT ANALYSIS OF LONG-ACTING INSULIN ANALOGUES IN THE PERSPECTIVE OF BRAZILIAN PUBLIC HEALTH SYSTEM**

Laranjeira FO, Silva EN, Pereira MG

University of Brasilia, Brasilia/DF, Brazil

Objectives: To estimate the incremental budget impact of the reimbursement of long-acting insulin analogues (LAIAs) for type 1 diabetes patients (T1DM) in Brazil. **METHODS:** A budget impact analysis (BIA) of LAIA in the Brazilian public health system was compared to NPH human insulin when performed. **RESULTS:** The analysis’ time horizon was 5 years. The target population used the methodology of epidemiological demand, considering estimates of the International Diabetes Federation: 11.6 million diabetics of 20-79 years old x 5% T1DM plus 31100 children per year and mortality 23.15/1000 adults per year. The overall mean insulin dose was obtained from trials. For the human insulin, we considered the values of last purchase price of the Ministry of Health. For both insulins, we got the average maximum sale price for government from CMED list. Then the bargaining power was calculated dividing the NPH’s maximum sale price by the Ministry’s purchase price, and we applied 50% of the bargaining power to the LAIA’s price. Market share was 50%, 60%, 70%, 80% and 80%. **RESULTS:** The incremental budget impact of LAIA would be $93 million in the first year, considering 50% of target population, and reaching approximately $432 million for 80% of patients. In 5 years the calculated budget impact was $617 million. The sensitivity analysis indicates the prevalence and analogues prices as variables. **CONCLUSIONS:** LAIA are available in Brazil since 2002, although to this day the public health system does not make it available to citizens. We can suggest that the reason for non-coverage is the considerable budget impact, nevertheless our analysis, more complex and with rational methodology, have shown less impact than the analysis used in the Ministry’s decision, which BIA was US $16 million for the coverage of LAIA.

**PDB26**

**THE NHS EXPENDITURE MANAGING SEVERE HYPOGLYCAEMIA EPISODES IN TYPE 2 DIABETIC PATIENTS IN PORTUGAL**

Laires PA1, Conceição J1, Araújo P2, Diores J1, Silva C2, Radicalis L3, Nogueira AM4

1The University of Texas at Austin, College of Pharmacy, Austin, TX, USA, 2CHI, Humana, Inc., Louisville, KY, USA

Objectives: Hypoglycaemia is an acute complication of diabetes that increases mortality, morbidity, and disease costs. We aim to estimate the annual NHS expenditure managing severe hypoglycaemia episodes in type 2 diabetic patients in Portugal. **METHODS:** HIPOS-ER (Hypoglycaemia in Portugal Observational Study – Emergency Room) study was an observational, cross-sectional, multicenter, observational study conducted in 34 centers within a period of 12 months (January 2013 - January 2014). Patient level data were used to quantify healthcare resource consumption related to emergency transport and care in diabetic patients. Unit costs for 2014 were extracted from official sources and reported in euros. **RESULTS:** A total of 245,706 admissions at the emergency room were registered in the participating hospitals. Deaths occurred covered by HIPOS-ER study of these, 0.074% had diabetes type 2 and were admitted due to an episode of hypoglycaemia meaning that theoretically 2,317 emergencies occur yearly in Portugal due to severe hypoglycaemia in Type 2 diabetic patients (out of an universe of 3,131,126 annual general emergencies in Portugal). Considering the care costs estimated per case, managing this type of hypoglycaemia (< ±479), we expect that around 3.4 millions of euros per year are spent in treating this diabetes related complication at emergency rooms of NHS Portuguese hospitals. **CONCLUSIONS:** Our estimate highlights the potential overall economic burden of severe hypoglycaemias in Portugal, meaning that this diabetes-related event must be taken in consideration by different healthcare stakeholders not only from strict clinical point of view, but also from an economic one. We conclude that severe hypoglycaemic events represent a substantial cost for society and in particular for the hospitals of the National Health Service.

**PDB27**

**COSTS FOR DIABETIC PATIENTS RECEIVING Dipeptidyl Peptidase-4 (DPP-4) INHIBITORS IN US MEDICARE AND COMMERCIAL INSURANCE PLANS**

Racati KL1, Worrel EF2, Luster M3, Mealy Y4

1The University of Texas at Austin, College of Pharmacy, Austin, TX, USA, 2CHI, Humana, Inc., Louisville, KY, USA, 3Humana Inc., Louisville, KY, USA

Objectives: The objective of this study was to compare the cost differences between a DPP-4 inhibitor (DPP-4i) and insulin in a patient taking DPP-4i in the real-world setting. Our hypothesis was that overall costs related to diabetes care were lower for patients taking DPP-4 inhibitors. **METHODS:** Claims were extracted from Humana Medicare or Commercial plan members with diabetes for a DPP-4-inhibitor between July 1, 2011 and March 31, 2013. The first prescription following a DPP-4-inhibitor prescription billed by the same provider was included. Both over- and under-treatment pose a threat to patients with type 2 diabetes mellitus.

**PDB22**

**RISK OF FRACTURE IN TYPE 2 DIABETES MELLITUS PATIENTS: META-ANALYSIS OF OBSERVATIONAL STUDIES**

Shah A1, Kumar S2, Silva RO2, Ferreira L2, Naidu M3, Dang A4

1MarksMan Healthcare Solutions LLP (HEOR and RWE Consulting), Navi Mumbai, India, 2S.J.M. College of Pharmacy, Chitradurga, India

Objectives: Patients with type 2 diabetes mellitus (T2DM) display a unique skeletal profile with increased fracture risk. Our objective was to identify risk factors associated with fracture risk in subjects with T2DM. **METHODS:** A systematic literature search was performed in Medline and EMBASE databases. “Abstracts” from annual scientific meeting of various diabetes and bone and mineral related societies were included. Both over- and under-treatment pose a threat to patients with type 2 diabetes mellitus.

**PDB23**

**HETEROGENEITY IN THE DEFINITION OF DRUG INDUCED HYPOGLYCAEMIA ACROSS RANDOMIZED CLINICAL TRIALS (RCTs) Conducted with Oral Antidiabetic Agents or Insulin. METHODS: RCTs included in the Canadian Agency for Drugs and Technologies in Health (CADTH) reports for the second-line and third-line therapy for the Diabetes were extracted. Exclusions: Definets for overall, major, minor, severe, and nocturnal hypoglycaemia were extracted from 76 RCTs. The extracted definitions were compared to the definitions of the American Diabetes Association (ADA) and European Medicines Agency (EMA). **RESULTS:** According to the ADA and the EMA, hypoglycaemia is defined as an event with a blood glucose (BG) ≤ 3.9 mmol/L. Only 4 out of 76 studies adhered to the ADA/EMA definition of hypoglycaemia. Generally, hypoglycaemia was defined as a status with BG ranging from 3 to 4.6 mmol/L. Only 17 out of 33 RCTs that defined severe hypoglycaemia adhered to the ADA/EMA definition. Severe hypoglycaemia was defined as a symptomatic condition that required the assistance of a third person for resuscitation or treatment or with or without a BG value ranging from <4 to <2 mmol/L. Not all studies were defined as patients being unable to treat themselves, with or without a BG value ranging from <3.1 mmol/L to ≤ 2.8 mmol/L. **CONCLUSIONS:** Compared to the ADA and EMA proposed definitions of hypoglycaemia (BG≤3.9 mmol/L), the studies included in our review had a substantial heterogeneity in their definitions of hypoglycaemia not only in terms of the BG values being used, but also with the...