

observational studies and Centre for Evidence Based Medicine checklists for any other study design. The present review is part of the GIFTS project funded by Seventh Framework Programme of European Commission. **RESULTS:** A total of 349 papers were identified, after title and abstract revision 76 full text were retrieved plus 8 identified through pearing. To date 67 full texts have been assessed, 49 excluded and 18 included. 14 (78%) were conducted in the UK. South Asian pregnant women were at higher risk of developing GDM (OR ranged 2-5.6) and intrauterine growth retardation (OR ranged 2-5) than European counterparts. These factors contributed to higher rates of stillbirth, perinatal and neonatal mortality and congenital anomalies detected in South Asian origin women. As well as higher rates of babies with vitamin D deficiency, hypocalcaemia, hyperinsulinemia, dyslipidaemia, hypoglycaemia and lower birthweight. Also higher risk of rapid weight gain between 12 to 24 months and 3 to 5 years in Asian infants was reported in two different papers. **CONCLUSIONS:** There are differences between Asian women living in Europe and European women during pregnancy, and their offspring, which as early life factors might explain higher prevalence of later metabolic syndrome and type 2 diabetes in Asian migrant population.

#### PDB22

##### PREDICTING THE FREQUENCY OF SEVERE AND NON-SEVERE HYPOGLYCAEMIA IN INSULIN TREATED TYPE-2 DIABETES SUBJECTS

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**OBJECTIVES:** Recent studies have quantified the resource implications associated with severe hypoglycaemia episodes (SHE) and non-severe hypoglycaemia episodes (NSHE). The objective of this study was to characterize the relationship between the frequency of SHE/NSHE and patient/therapy characteristics in insulin treated type-2 diabetes mellitus (T2DM) patients. **METHODS:** We conducted a literature review of the MEDLINE database for insulin-based T2DM clinical trials where sulphonylurea usage was also reported between June 1, 2007 and June 1, 2012. Patient demographics, treatment effects and treatment type were extracted and the SHE/NSHE rate per 100 patient years (PY) was modeled via a log-linear regression model using R. **RESULTS:** Data were extracted from 82 studies for a total of 155 trial arms meeting the search criteria; treatment regimes were categorized into basal analog (30%); bolus analog (4%); basal bolus (24%); biphasic analog (25%); biphasic human (8%) and NPH (10%). Mean (standard deviation) age was 57.9 (3.8) years; 10.2 (2.4) years duration of diabetes; 8.8% (0.7) baseline and 7.5% (0.5) end-of-study HbA1c respectively. Mean reported NSHE/100 PYs was 929.8. The final regression model was  $NSHE/100PY = \exp(14.771 - 0.088 \times \text{age} - 0.667 \times \text{baseline HbA1c} + 0.427 \times \text{HbA1c reduction} + 0.189 \times \text{duration diabetes} + 0.007 \times \% \text{ study allowed sulphonylurea} - 0.545 \times \text{basal analog insulin})$  with an  $R^2$  goodness of fit of 0.226. Mean reported SHE/100 PYs was 5.9. The final regression model was  $SHE/100PY = \exp(10.794 - 0.101 \times \text{age} - 0.723 \times \text{baseline HbA1c} + 0.638 \times \text{HbA1c reduction} + 0.163 \times \text{duration diabetes} + 0.768 \times \text{biphasic insulin} - 1)$  with an  $R^2$  of 0.219. **CONCLUSIONS:** This study provides a basis for predicting the number of SHE and NSHE in insulin treated T2DM subjects. When linked to resource and quality life, these equations may facilitate the improved estimation of the health economic burden associated with SHEs and NSHEs.

#### PDB23

##### ANTI-DIABETIC MEDICATIONS RELATED SEVERE HYPOGLYCAEMIA RISK IN DIABETES TYPE 1 AND TYPE 2 – A SYSTEMATIC REVIEW OF OBSERVATIONAL STUDIES

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**OBJECTIVES:** Severe (requiring assistance from another individual) hypoglycaemic events (SHEs) are important from both clinical and economic perspectives. The aim was to assess treatment-related SHEs risk in different treatment regimens in type 1 and 2 diabetes. **METHODS:** Anti-diabetic treatments were stratified into six groups: basal-bolus (BB); basal in combination with oral therapy (BOT); insulin pumps; biphasic insulin; sulphonylureas; other than SU oral antidiabetic drugs (OADs). Insulin treatments were further split into analogues (IA) and human insulins (HI). The systematic review of Medline, EMBASE and Cochrane databases was conducted for recent ( $\leq 10$  years), large ( $n \geq 100$ ), observational studies. Data on time horizon, participants number and SHEs occurrence were extracted. Using a random effects Poisson model within MCMC framework we estimated the SHEs rates. **RESULTS:** In the systematic review 5220 publications were found, 525 full texts evaluated and 101 articles included (55 trials). The following average SHE/year (No of studies; 95%CI) were estimated: Type 1: BB with IA as the basal component: 0.53 (7; 0.29–1.18); BB with HI: 1.10 (6; 0.58–2.71); pump treatment: 0.18 (14; 0.13–0.25); biphasic insulin: 1.10 (0.58–2.71). Type 2: BOT with IA as the basal component: 0.13 (11; 0.04–1.17); BOT with HI: 0.21 (7; 0.08–0.88); BB with IA: 0.01 (6; 0.003–0.25); BB with HI: 0.56 (3; 0.16–9.65); biphasic IA: 0.10 (12; 0.05–0.26); biphasic HI: 0.20 (6; 0.07–0.93); sulphonylureas: 0.05 (6; 0.02–0.14); OADs: 0.01 (0.001–0.008). The differences in the SHEs risk among regimens were significant at a 95% level. **CONCLUSIONS:** The SHEs risk differs in both type 1 and 2 diabetes across various treatment regimens. HI was found to increase the SHEs risk compared to IA. Limited availability of studies and heterogeneous data make it difficult to come up with precise rate estimation for typical anti-diabetic treatment regimens.

#### DIABETES/ENDOCRINE DISORDERS – Cost Studies

#### PDB24

##### ESTIMATION OF THE COST OF COMPLICATIONS RELATED TO GLYCATED HEMOGLOBIN IN THE ITALIAN DIABETES TYPE 1 POPULATION

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**OBJECTIVES:** In Type 1 diabetic (T1D) patients high values of glycated hemoglobin (HbA1c) have been shown to be associated with higher risk of complications leading to high costs to the National Health Care System (NHS). The aim of this analysis is to evaluate the economic impact of poor glycaemic control, and the potential savings associated with better glycaemic control in the Italian T1D population. **METHODS:** A probabilistic model using published risk-curves was developed to project incidence and progression of diabetes-related complications associated with different HbA1c levels over 1-year and 5-year time-horizon in T1D patients. Associated cost of retinopathy, nephropathy, neuropathy, cardiovascular disease, diabetic ketoacidosis and severe hypoglycemia in the Italian setting were used to estimate the economic impact of complications in each HbA1c interval from the NHS perspective. Subsequently the results of the simulation were translated to the entire Italian T1D population stratified by HbA1c level accordingly to published 2012 data. **RESULTS:** Estimated cost per patients of diabetes-related complications in the first year of occurrence, stratified by HbA1c intervals, ranged from 4,463€ for HbA1c  $\geq 10\%$  to 2,006€ for HbA1c between 7% and 8%. A 5 year follow up analysis was also conducted. A treatment strategy able to reduce HbA1c level from  $\geq 10\%$  to 9% could lead to potential savings of 1,342€ per patients in the first year of treatment. Considering the total T1D Italian population, improving HbA1c to  $< 8\%$  in the first year would result in a potential savings of about 17 million euros. **CONCLUSIONS:** The economic impact of diabetes-related complications in the Italian setting is significant. Consequently the potential savings for the NHS derived from the implementation of strategies aimed at improving HbA1c in T1 should be considered. Moreover the greater the reduction of HbA1c obtained the greater the associated savings.

#### PDB25

##### COST-COMPARISON BETWEEN DIFFERENT TREATMENT REGIMENS IN DIABETES MELLITUS IN GERMANY BASED ON LONG ACTING INSULINS

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**OBJECTIVES:** Cost comparison between different basal insulin regimens (Glargine vs. Detemir vs. NPH-insulin) in diabetic patients in Germany under real-life conditions. **METHODS:** The analysis is based on IMS LRx-database (2011). This representative patient tracking tool covers nearly 60 million insurants and includes more than 500 million drug prescriptions per year (including consumables). Patients with at least two prescriptions of basal insulin (Glargine, Detemir or NPH-insulin) in 2011 (January – December) and at least one prescription of any type in 2010 and 2012 were considered eligible. Costs included basal and bolus insulin, oral antidiabetic drugs, test strips, needles and lancets and were estimated by ex pharmacy prices (Lauer Taxe) minus legally defined rebates according to §130 a of social security code (SGB V). **RESULTS:** A total of 542,438 patients were allocated to either Glargine (207,506 patients) or Detemir (90,671 patients) or NPH (244,261 patients). The mean annual treatment costs per patient are 1,211 € (Glargine), 1,224 € (NPH insulin) and 1,572 € (Detemir). A breakdown at the level of different sick funds shows a similar pattern of annual treatment costs per patient of the three basal insulin regimens. The acquisition costs of basal insulin is considerably higher for Glargine (380 €) and Detemir (448 €) compared to NPH-Insulin (253 €). The cost of bolus insulin is lower in the Glargine group (305 €) compared to NPH-insulin (419 €) and Detemir (493 €). Costs of consumables (test strips, needles, lancets) are lowest in the in the Glargine group (395 €) due fewer insulin applications compared to Detemir (509 €) and NPH insulin (461 €). **CONCLUSIONS:** Mean annual treatment costs are lowest with Glargine followed by NPH-insulin, whereas Detemir based regimens are 30% more expensive under real life conditions. The results are in line with previous cost analyses in diabetic patients in Germany [1-3]

#### PDB26

##### A COMPARISON OF THE ECONOMIC BURDEN AND HEALTH CARE UTILIZATIONS OF VETERAN PATIENTS DIAGNOSED WITH DIABETES IN THE UNITED STATES

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**OBJECTIVES:** To assess the economic burden and health care utilizations of diabetes in the U.S. veteran population. **METHODS:** Adult ( $\geq 18$  years of age) patients diagnosed with diabetes (International Classification of Disease 9<sup>th</sup> Revision Clinical Modification [ICD-9-CM] code 250.x0 or 250.x2) were identified from the dataset between October 1, 2009 through September 30, 2011. The first diagnosis date was designated as the index date. A comparator group was created consisting of patients without diabetes but of the same age, region, gender and index year, and matched by baseline Charlson Comorbidity Index. The index date for the comparator group was randomly selected to minimize selection bias. Continuous medical and pharmacy benefits 1 year pre- and 1 year post-index date were required for patients in both groups. One-to-one propensity score matching (PSM) was applied to compare health care costs and utilizations during the follow-up period between the diabetes and comparator groups, adjusted for baseline demographic and clinical characteristics. **RESULTS:** A total of 1,427,948 patients were identified for the diabetes and comparator cohorts. After applying 1:1 PSM matching, a total of 340,933 patients were matched from each group, ensuring well-balanced baseline characteristics. Patients diagnosed with diabetes were more likely to report inpatient (8.93% vs. 2.09%,  $p < 0.01$ ), emergency room (13.66% vs. 5.61%,  $p < 0.01$ ), outpatient (99.63% vs. 53.78%,  $p < 0.01$ ), and pharmacy visits (87.13% vs. 52.69%,  $p < 0.01$ ). They also incurred higher health care costs, including inpatient (\$3,031 vs. \$582,  $p < 0.01$ ), emergency room (\$137 vs. \$51,  $p < 0.01$ ), outpatient (\$3,375 vs. \$1,272,  $p < 0.01$ ), pharmacy (\$708 vs. \$293,  $p < 0.01$ ) and total costs (\$7,113 vs. \$2,148,  $p < 0.01$ ) than the comparator group. **CONCLUSIONS:** U.S. veteran patients diagnosed with diabetes reported a significantly higher economic burden compared to the matched controls over a 12-month period.