the 6 agencies (9 publications) that evaluated DPP-4 inhibitors, 2 recommended the drug not to be listed or funded (CADTH, AHTAPol) and 4 recommended unrestricted use (PBAC, SMC, CVZ and NICE). The most common reason for agency's disqualification for listing/funding was insufficient information on the effectiveness and cost-effectiveness of the specified patient population. The agencies evaluated more than 100 HTAs on the endocrine nutritional and metabolic therapeutic area, approximately half of them (49 projects) concern diabetes, 21 of which evaluate pharmacological treatment of diabetes (8 countries, 11 agencies). CONCLUSIONS: Diabetes prevalence is on the rise, attracting attention from health care agencies. Despite health technology assessment data sources variable outcomes suggest to us that agencies are applying different weightings in their assessment process. The apparent failure to demonstrate effectiveness in specified populations suggests late segmentation by manufacturers and insufficient insurancerequiring other data. This is often due to late payer requests for such analyses motivated by financial considerations. Early segmentation and engagement with payers is thus critical for HTA success.

**PD76**

**ETHICAL ANALYSES IN HEALTH TECHNOLOGY ASSESSMENTS OF DIABETES TREATMENTS**

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OBJECTIVES: Health Technology Assessment (HTA) is mostly known for its health economic properties even though it is a multidisciplinary form of policy research examining short- and long-term consequences of the application of a health technology. There is an increased focus on ethical analyses on HTA. A descriptive analysis was conducted on diabetes HTA reports describing ethical analyses. METHODS: The NHS Centre for Reviews and Dissemination HTA database (http://www.crd.york.ac.uk/HTAweb) was searched (1991-2009) using the keyword ‘diabetes’. HTA reports in English language were included as they were included in a search of type of ethical analyses. RESULTS: Of 263 HTA reports identified in the initial search, 60 met the inclusion criteria. 4 reports included a type of ethical analysis (2 from CADTH, Canada; 1 from AHTA, Australia and 1 from NZHTA, New Zealand). CADTH conducted ethical analyses on short- and long-acting insulin analogues respectively, concluding that both types of insulin analogues did not exacerbate—might even better—the psychosocial issues of diabetes, however more quality-of-life evidence was needed. In AHTA’s assessment of a continuous glucose monitoring device and assessing diabetes treatments were included and screened for any insurancerequiring data. This is often due to late payer requests for such analyses motivated by financial considerations. Early segmentation and engagement with payers is thus critical for HTA success.

**PD77**

**BASELINE CHARACTERISTICS OF PATIENTS BEGGINING BASAL, BASAL PLUS SHORT-ACTING, SHORT-ACTING OR PREMIX INSULIN**

From the CREDIT Study

Home P1, Blondeau L1, Admane K4, Vespasian G1

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OBJECTIVES: The ongoing Cardiovascular (CV) Risk Evaluation in people with Type-2 diabetes mellitus (T2DM) on Insulin Therapy (CREDIT) study is assessing the effect of insulin on the risk of vascular events, which can be reduced via long-term glycaemic control. METHODS: CREDIT is a 4-year, 314 centre, non-interventional trial in North America, Europe and Asia. It includes 3031 people with T2DM who recently started basal and/or short-acting insulin, premix insulin or another insulin type. This analysis examines and compares the characteristics between groups starting basal (n = 1563), basal plus short-acting (n = 444), short-acting (n = 221), premixed (n = 700) or another (n = 103) insulin. RESULTS: Demographic and diabetes characteristics were reasonably balanced between the insulin groups, although those receiving basal plus short-acting insulin or premix had a trend to higher baseline HbA1c levels vs other insulin types (basal, 9.2 ± 1.8%; basal plus short-acting, 10.1 ± 2.2%; short-acting, 9.4 ± 2.0%; premix, 9.9 ± 2.0%; other, 9.1 ± 2.0%). While the majority had previously used oral glucose lowering drugs (65%), basal 97%, basal plus short-acting, 83%; short-acting, 83%; premix, 94%; other, 83%), differences in the numbers continuing OGLDs when beginning insulin were found. Continued use of OGLDs was highest with basal insulin (89%) versus the other insulins (basal plus short-acting, 86%; short-acting, 85%; premix, 62%; other, 83%). However, the distribution of types of OGLD used before insulin was similar between the groups. There are no clear patterns in CV risk profile by insulin type. Previous diagnosis of hypertension (basal, 71%; basal plus short-acting, 65%; short-acting, 57%; premixed, 38%), family history of CV disease (basal, 29%; basal plus short-acting, 25%; short-acting, 21%; premix, 23%; other, 14%) and body mass index tended to be lower in the short-acting insulin group. However, triglyceride levels were lower in the short-acting and ‘other’ insulin groups vs premix, basal and basal plus short-acting groups. CONCLUSIONS: People starting different insulins have somewhat different clinical characteristics, which may confound attempts to compare future vascular outcomes between regimens.

**PD78**

**DIFFERENCES IN THE CHARACTERISTICS OF PEOPLE WITH TYPE 2 DIABETES STARTING INSULIN IN THE NORTH, SOUTH AND EAST OF EUROPE: DATA FROM THE CREDIT STUDY**

Marre M1, Home P1, Vespasian G1, Admane K1, Blondeau L1

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OBJECTIVES: Maintaining long-term glycaemic control with insulin therapy can reduce the risk of vascular events associated with Type-2 diabetes mellitus (T2DM). The Cardiovascular (CV) Risk Evaluation in people with T2DM on Insulin Therapy (CREDIT) study is an ongoing 4-year, non-interventional trial in 314 centres across North America, Europe and Asia. METHODS: People with T2DM who recently started insulin were included. Here we report variation in baseline characteristics of participants in eastern vs northern vs southern Europe. RESULTS: Marked differences in participant characteristics were found between eastern Europe (n = 735), northern (n = 460) and southern Europe (n = 647), including proportion of males (25 vs. 61 vs. 56%), diabetes duration (8 vs. 5 vs. 13 ± 9 years), age (35.8 vs 8 vs. 63 ± 11 vs. 63 ± 11 years) and HbA1c (9.7 ± 1.9 vs. 9.1 ± 2.0 vs. 9.3 ± 1.9%). Combinations of oral glucose-lowering drugs were common before insulin; sulfonylureas were dose-reduced if possible. On average, 93% received insulin; glucose medications before insulin initiation, most commonly ARBs. People in eastern Europe had a greater family history of CV disease, were less physically active, but were not more obese (BMI 30.7 ± 5.4 vs. 31.5 ± 6.3 vs. 29.6 ± 5.9 kg/m²). Rates of admission were lowest in south eastern Europe. HDL cholesterol was lowest in northern Europe and in females was highest in eastern Europe. LDL cholesterol was highest in southern Europe. Total cholesterol levels were lowest, but triglyceride levels were highest in northern Europe. Smoking was less prevalent in eastern Europe. Most people began with a basal insulin regimen (60 vs 63 vs. 61%), more people used meal-time insulins in eastern Europe (19 vs. 11 vs. 17%), and pre-mixes in northern Europe (22 vs. 18 vs. 13%). CONCLUSIONS: Baseline characteristics of people starting insulin reveals some striking differences between European regions; how these translate into CV events as the study progresses will be of interest.

**PD79**

**DO PEOPLE BEGINNING BASAL INSULIN HAVE A DISTINCT CLINICAL PROFILE COMPARED WITH THE OVERALL POPULATION IN THE CREDIT STUDY?**

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OBJECTIVES: The Cardiovascular Risk Evaluation in people with Type-2 diabetes mellitus (T2DM) on Insulin Therapy (CREDIT) study is evaluating the effect of insulin on the risk of vascular events, which can be reduced via long-term glycaemic control. METHODS: CREDIT is a 4-year, 314 centre, non-interventional trial in North America, Europe and Asia. It includes 3031 people with T2DM who had recently started basal, short-acting or premix insulin, over half of whom received basal insulin alone. This analysis examines the baseline characteristics of people initiating insulin therapy and compares them with those of the wider CREDIT population. RESULTS: The mean starting dose of basal insulin was 14.7 IU/day, administered on average 16% of patients. Of these, 61% took their injection at bedtime, 21% at breakfast, 17% at dinner and 1% at lunch. Over 90% used pen devices, split equally between disposable (46%) and reusable devices (45%). Demographic and clinical characteristics, including macrovascular and cardiovascular risk profiles, were broadly similar between the basal insulin subgroup and the overall group of participants (basal insulin subgroup vs total population: males, 48 vs 51%; age, 62 ± 11 vs 6 ± 10 years; T2DM duration, 10 ± 7 vs 11 ± 8 years; HbA1c, 9.2 ± 1.8 vs 9.5 ± 2.0; prior use of oral glucose lowering drugs [OGLDs], 97 vs 93%). Use of OGLDs with insulin tended to be higher in the basal insulin subgroup (any OGLD, 89 ± 70%, any biguanides, 54 ± 50%, sulfonylureas, 63 ± 43%). CONCLUSIONS: The one notable difference between the groups was that those who began using basal insulin alone were more heavily treated with OGLDs beforehand than in the overall population, most commonly biguanides and sulfonylureas. This suggests that they required lower doses of insulin and lower intensity of glycaemic management than people starting on other types of insulin.

**PD80**

**MEASURING GLYCOSYLATED HAEMOGLOBIN LEVELS IN PATIENTS WITH DIABETES: IMPACT OF LOWER QOF TARGETS ON ACHIEVEMENT OF CLINICAL INDICATORS AND QOF POINTS**

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OBJECTIVES: The 2008/09 Quality and Outcomes Framework (QOF) indicators for measuring glycosylated haemoglobin (HbA1c) levels are DM20 and DM07, which measure percentage of diabetic patients with HbA1c of either 7.5 or less or 10 or less respectively. New QOF clinical indicators have been agreed for 2009/10: DM23
replaces DM20 measuring percentage of patients with HbA1c less than 7; DM24 (new indicator) measuring percentage with HbA1c less than 8; DM23 replaces DM07 measuring percentage with HbA1c less than 9. The analysis objective is to estimate likely achievement of these new indicators and assess impact on QOF points. METHODS: Using achievement of current clinical indicators, reported by NHS Information Centre, is 66.8% and 92.3%, with average points achievement of 98.3% (16.7 from 17) and 97.9% (10.8 from 11) for DM20 and DM07 respectively. Mean HbA1c of 6.9 (standard deviation 1.5; 1-2 years after entry to study) was taken from UKPDS 56 distribution, values (average diabetes QOF register) were generated from this distribution and percentage achievement of current and proposed indicators was calculated. This simulation was repeated 8,294 times (number of QOF practices) and average achievement for each indicator was noted. RESULTS: Average achievement of current indicators UKPDS 56 distribution was estimated at 65.5% and 98.1% for DM20 and DM07 respectively, comparing favourably with reported results. Average achievement of proposed QOF indicators was estimated at 52.7%, 76.8% and 91.9% with maximum points (35 in total) awarded at 50%, 70% and 90% for DM23, DM24 and DM25 respectively. CONCLUSIONS: Although the QOF targets for HbA1c are lower, the average percentage achievement is estimated to reach the level required for maximum QOF points. However, since the average is close to the maximum payment level for DM23 and DM25 a number of practices are unlikely to reach this unless increased reductions in HbA1c are achieved.

THE ROAD TO INSULIN—A PATH OF TREATMENT ANALYSIS OF REAL-WORLD PHARMACY DATA FROM THE USA

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OBJECTIVES: Understanding current and new paths of treatment (POT) in diabetes is pivotal for estimating budget impacts when new antidiabetic agents are introduced to pharmacy formularies. Although diabetes treatment guidelines exist to guide prescribers, very limited real-life data are available to illustrate actual POT’s for patients initiating insulin treatment. The aim of this study was to establish the most prevalent POT’s for insulin initiation using real-world US pharmacy data. METHODS: Medicaid, Cash and 3rd party payer pharmacy claims were obtained from SDI. A patient’s first insulin Rx between October and December, 2004 served as an index Rx. A 6 month look-back identified prior treatments and a 3 year look-forward tracked changes from the index Rx. To be eligible for analysis, patients had to have no insulin Rx in the look-back and be in the SDI database in the first and last quarter of observation. The pattern of payers and prescribers were identified along with the most frequent POT’s for each step. The average duration for each step was analyzed.

RESULTS: Out of 351,887 patients with an index insulin Rx, 78,213 had no insulin in the look-back. Claims were paid by Medicaid (13%), cash (4%), and 3rd party (83%). The top-10 combinations prior to the index insulin constituted 96% of the data. The top 3 were Metformin(MET)+ Sulfonylurea(SU) (18%), Met alone (17%) and SU alone (13%). The top-10 combinations initiating index insulin constituted 59% of the data. The top 3 were MET + SU + basal insulin (11%), MET + SU + TZD + basal insulin (11%), and SU + basal insulin (6%). On average, patients initiating insulin were 230 days without changing their therapy. CONCLUSIONS: Based on real-world data, the small number of therapy combinations explains the POT’s before insulin initiation. Upon initiating insulin treatment, combinations are more varied, although most include basal insulin.

PREDICTORS OF EFFECTIVENESS WITH LOPINAVIR/RITONAVIR (LPV/R) SINGLE AGENT THERAPY (SAT) TO IMPROVE CLINICAL OUTCOMES IN HIGH RISK HIV+ PATIENTS IN AN URBAN CLINIC

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OBJECTIVES: LPV/r SAT may durably suppress HIV and maintain immunologic response in multiple trial settings, but criteria for improved clinical outcomes have not been determined. Our objective was to identify the LPV/r SAT use and predictors of viral suppression in an urban clinic setting. METHODS: A retrospective, longitudinal cohort study was conducted of all patients ≥18 years old with ≥2 HIV-1 RNA (“viral load”), VL measurements starting LPV/r SAT from 2003-2007 at a large urban HIV clinic. Inclusion criteria: prospective clinical trial enrollment or missing data. Variables (demographics, baseline plasma VL and CD4, previous HAART, adherence, and missed clinic visits) evaluated by univariate and stepwise logistic regression to determine predictors of virologic suppression (achievement and/or maintenance of VL <50 copies/mL). RESULTS: Ninety-one patients met inclusion criteria (73% male; 34% black, 35% Caucasian, and 11% Hispanic). Mean age was 42.4 years, median CD4 prior to SAT 290 cells/mm³, and median VL 8960 copies/mL. Reasons for SAT (provider and patient perspective): easy regimen (29%), simplification/maintenance (26%), antiretroviral toxicity (21%), and adherence (21%). In patients with 26 months follow-up (n = 82), 37 were HAART-naïve and 45 had ≥1 previous HAART regimen. Overall, 73% of HAART-naïve and 47% of patients with ≥1 previous HAART regimen achieved/maintained viral suppression. In univariate analyses, age, adherence, ethnicity, low VL, high CD4, and AIDS status were significant predictors (p < 0.05). Regression analysis indicated age > 50 years (OR 5.2 [95% CI, 1.1–18.4]), white ethnicity (OR 2.5 [1.1–8.3]), and no AIDS (OR 3.0 [1.2–12.5]) were independently associated with viral suppression (p < 0.05). SAT was stopped in 1791 patients for reasons: medication intolerance, poor adherence, drug toxicity, or drug cost. CONCLUSIONS: Incidence of viral suppression was similar to prospective controlled trials in HAART-naïve patients. Older patients with no/mild immunosuppression and limited prior antiretroviral experience may be better candidates for LPV/r SAT. Larger, prospective evaluations are needed.

INFECTION – Clinical Outcomes Studies

PDB1

INFECTION – Clinical Outcomes Studies

FRENCH OBSERVATIONAL COHORT OF HIV-1 INFECTED PATIENTS TREATED WITH ENFUVIRIDE: LONG-TERM EFFICACY AND SAFETY (ZOOM)


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OBJECTIVES: Enfuvirtide is part of a novel class of agents known as fusion inhibitors approved following the phase III TORO trials. The objective of ZOOM cohort was to assess in real life setting long term efficacy and safety of enfuvirtide in HIV-1 patients. METHODS: ZOOM is a multicenter, observational, longitudinal, prospective French study conducted from September 2004 to September 2006. The main objectives were immuno-virological and clinical assessments during the treatment and after a 2 year follow-up. Secondary objectives were patient’s characteristics, drug treatment modalities, safety and quality of life. RESULTS: During this period, 364 patients were included, their characteristics were as follow: mean age : 45 ± 9 years, median viral load: 4,70 log10 copies/mL, median CD4 count : 155 cell/mm³; AIDS defining events : 52%; antiretroviral pre-treated patients: 97% since a mean of 10 ± 3 years. These characteristics were similar to the HIV French Hospital database. At 24 months, 43% of treated patients had an undetectable HIV plasma viral load (threshold 400 copies/mL) and 39% had a CD4 increase of at least 100 cell/ mm³ (versus 27% and 32% respectively in the TORO trial). The most common adverse event was injection site reaction (91% versus 98% in TORO). In addition, the prob-