RESULTS: The incidence of major bleeding among 4005 Medicare beneficiaries who underwent an incident surgery was 4.7%. Patients experiencing major bleeding had longer hospital lengths of stay (11.5 vs. 9.8 days, $P < 0.01$), longer ICU lengths of stay (10 vs. 7.7 days, $P < 0.01$), were more likely to die in the hospital (OR = 1.95, $P < 0.01$), and were responsible for significantly higher charges (+$18,512, $P < 0.01$) and reimbursements (+$2642, $P < 0.01$). Over two years of follow-up, patients with major bleeding were more likely to experience renal failure (OR = 1.40, $P = 0.06$), were more likely to die ($P < 0.01$), and incurred higher medical care costs ($P < 0.05$). **CONCLUSION:** Patients who experienced major bleeding during CABG requiring CPB tended to have poorer immediate and longer-term outcomes. Results suggest that interventions to prevent major bleeding during cardiac surgery may diminish or prevent these negative clinical and economic outcomes.

CV4

CAN TWO A'S RESULT IN A FAILURE?: EFFECT OF ASPIRIN ON THE RISK OF HEART FAILURE HOSPITALIZATIONS IN CHF PATIENTS ON ACE INHIBITORS

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OBJECTIVE: Aspirin use may negatively interact with the effect of ACE inhibitors in treating heart failure. Hence, we sought to determine whether aspirin increases the risk of heart failure hospitalizations in non-elderly CHF patients on ACE Inhibitors. **METHODS:** A retrospective analysis of the 2001 Georgia Medicaid claims data was performed. Patients between 18–64 years of age who received a diagnosis of CHF (ICD-9 CM = 428.XX) and filled at least one prescription for ACE Inhibitors between January 1, 2001 and June 30, 2001 were included in the study. Among these patients, those receiving aspirin were classified as the exposed group and patients not receiving aspirin were classified as the unexposed group. Hospitalization due to heart failure was assessed between July 1, 2001 and December 31, 2001. Multi-variable logistic regression provided adjusted estimates of the aspirin effect, with nonusers as the reference group, after controlling for demographic factors, co-morbidities and co-medications. **RESULTS:** One thousand four hundred fourteen patients were identified. The total number of aspirin users was 178 (12.58%). Average age was 51.36 years and most patients were females (66.5%). Also, most of the selected patients were African Americans (57.1%). The unadjusted odds ratio for exposure to aspirin was 1.798 (95% CI 1.097–2.896) and the adjusted odds ratio was 1.782 (95% CI 1.074–3.009). **CONCLUSION:** Aspirin use was associated with a greater risk of hospitalization due to HF in patients taking ACE Inhibitors. Hence, even in non-elderly CHF patients, a caution should be exercised when prescribing aspirin concomitantly with ACE inhibitors.

DIABETES OUTCOMES RESEARCH

DB1

REAL-WORLD SIX MONTH OUTCOMES OF PATIENTS INITIATING EXENATIDE IN A PRIMARY CARE ELECTRONIC MEDICAL RECORD DATABASE

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OBJECTIVE: This study evaluated real world outcomes of A1C and weight in patients with type-2 diabetes (T2DM) initiating exenatide therapy. **METHODS:** Patient data were extracted from the General Electric (GE) electronic medical record (EMR) research database from January 1, 2000 through September 30, 2007. Patients were ≥18 years old with T2DM defined by ICD-9 codes, ≥2 fasting blood glucose levels ≥126 mg/dL, or glycosylated hemoglobin (A1C) over 7.0%. Patients had prescription orders in the previous 395 d for metformin (MET), a sulfonylurea (SU) or a thiazolidinedione (TZD) as monotherapy or in combination. Baseline A1C, weight and BMI were documented 45 d prior to 15 d post-exenatide initiation and ±45 d at 6 mo post-exenatide initiation. **RESULTS:** For the 2086 patients with 6 mo of follow-up data, baseline mean (±SD) A1C was 8.4 ± 1.2%, weight was 243.4 ± 54.8 lbs and BMI was 38.5 ± 7.9 kg/m^2. Upon initiation of exenatide, 363 (17.4%), 147 (7.1%) and 84 (4.0%) were on MET, SU or TZD monotherapy respectively, 524 (25.1%) and 257 (12.3%) were on MET with TZD or SU, and 711 (34.1%) were on all three. Overall A1C change at 6 mo (n = 878) was –0.7%. When exenatide was added to MET, SU or TZD monotherapy, changes were –0.9% ($p < 0.0001$), –1.0% ($p < 0.0001$) and –0.8% ($p < 0.0032$) respectively. A1C lowering ranged from –0.5% to –0.8% with multiple oral antidiabetic drugs (OADs) ($p < 0.0001$). Overall weight loss (n = 1784) was –6.1 lbs ($p < 0.0001$). In the 6 mo following addition of exenatide to prior monotherapy, 14%, 23% and 45% of patients discontinued MET, SU and TZD respectively. Similar discontinuations were seen in the multiple OAD groups. **CONCLUSION:** The average baseline A1C (8.4%) and BMI (38.5 kg/m^2) is high in this primary care T2DM population, suggesting difficulty in the real world to achieve A1C and body weight goals. Exenatide therapy demonstrated significant reductions in A1C and weight over 6 mo with decreases in concomitant medications.

DB2

COST-EFFECTIVENESS ANALYSIS OF PREGABALIN FOR THE MANAGEMENT OF NEUROPATHIC PAIN ASSOCIATED WITH DIABETIC PERIPHERAL NEUROPATHY IN MEXICO

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OBJECTIVE: Neuropathic pain is a chronic condition that causes functional impairment in many areas of life and it occurs frequently with diabetes. The aim of this study was to analyze the cost-effectiveness of different treatments in managing diabetic peripheral neuropathy from the health care payer's perspective. **METHODS:** A four-state stochastic Markov model was performed to estimate costs and effectiveness. The Markov model includes several stages related to functional disability (mild-pain, moderate-pain, severe-pain and death). Effectiveness was assumed as the percentage of patients with no or mild pain (pain score <4) at the end of the follow-up period (one-year).Transition probabilities were taken from national and international published literature. Comparators used in the assessment were carbamazepine (200–600 mg/day), amitriptyline (100–150 mg/day), gabapentin (2400–3600 mg/day) and pregabalin (300–600 mg/day). Resource use and costs were obtained from hospital records (n = 1000) from the Social Security Mexican Institute (IMSS) and official institutional databases. Costs include emergency, outpatient and inpatient services, drugs, procedures, etc. The model was calibrated. Probabilistic sensitivity analyses were performed employing bootstrapping techniques and acceptability curves were constructed. **RESULTS:** The highest percentage of patients

with no or mild pain during the follow-up period was obtained by pregabalin (59.6%;CI95% 59.0%–60.2%); followed by gabapentin (49.2%; CI95% 48.7%–49.7%); amitriptyline (47.6%; CI95% 47.1%–48.1%) and carbamazepine (34.4%; CI95% 34.1%–34.8%). The annual expected mean costs per patient were US$3001.4 (CI95% US$2956.4–US$3046.3); US$4,707.7 (CI95% US$4689.9–US$4723.6); US$2814.4 (CI95% US$2783.4–US$2845.5) and US$3701.9 (CI95% US$3687.2–US$3716.6); respectively following the order above. The ICER's of pregabalin vs. carbamazepine (baseline), gabapentin and amitriptyline were -US$700.5 (CI95% -US$670.4:-US$730.7), -US$1706.4 (CI95% -US$1677.3:-US$1733.4) and US$186.9 (CI95% US$173.1–US$200.8); respectively. Using acceptability curves (WTP US$5000–US$50,000), pregabalin showed a probability between 90–99% to be the treatment most cost-effective. **CONCLUSION:** In Mexico, pregabalin showed to be a cost-saving therapy when is compared with carbamazepine and gabapentin; and cost-effective vs. amitriptyline in the management of neuropathic pain.

DB3

REAL-WORLD ANALYSIS OF PERCENT OF PATIENTS WITH TYPE 2 DIABETES ACHIEVING GLYCEMIC GOAL WITH INSULIN GLARGINE

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OBJECTIVE: The primary aim of type 2 diabetes (T2D) therapy is helping patients achieve glycemic goals (A1C < 7%) as recommended by the ADA. In the recent randomized controlled trials 4-T and INITIATE, patients treated with basal insulin alone achieved goal 28% and 40% of the time, respectively, despite progressive insulin titration. In this retrospective cohort study using a large, US commercial health plan claims database, we describe the clinical effectiveness of newly-prescribed basal insulin glargine (IG) in insulin-naive patients. **METHODS:** A total of 13,154 insulin-naïve (not prescribed insulin in previous 6 mo) patients were identified with a new prescription claim for IG between January 1, 2004 and June 30, 2006, ≥6 mo of pre-index eligibility (first claim = index date), ≥12 mo of post-index eligibility, and ≥18 y old. **RESULTS:** From this cohort, 7730 (59%) patients had no other insulin claims other than IG in the entire post-index period. All patients with baseline (100 d pre-index) and post-index (60–365 d) A1C data available and baseline A1C≥7.0% were analyzed (n = 313; mean baseline A1C (±SD) = 9.8 ± 2.1%). Mean (±SD) age was 52 ± 8 y (41% female; 3%≥65 y). In this cohort of patients who did not add any additional insulin (n = 313), 27% achieved A1C < 7% in the post-index period (mean [min,max] time index to post-index A1C = 238 d [63,365]). Mean (±SD) post-index A1C was 8.2 ± 1.9%. **CONCLUSION:** In this real-world analysis of patients initiated on IG, the percentage of patients achieving A1C < 7.0% and mean post-index A1C indicate that most patients do not achieve recommended glycemic targets—results which mirror controlled clinical studies. In addition, more than half of patients initiating IG did not supplement with additional insulin therapy over the course of the first year of therapy, despite not reaching glycemic goals. Because the contribution of post-prandial glucose to A1C increases as A1C approaches goal, agents targeting fasting glucose alone, like IG, may be insufficient in helping patients with T2D achieve glycemic goals.

DB4

RETROSPECTIVE STUDY OF TYPE 2 DIABETES MELLITUS (T2DM) PATIENTS NOT OPTIMALLY CONTROLLED BY METFORMIN MONOTHERAPY

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OBJECTIVE: The American Diabetes Association (ADA) recommends metformin as first line treatment for T2DM. As diabetes is a progressive disease, patients will ultimately need additional therapies to reach glycemic goals. Little information has been published that describes what happens to patients not optimally controlled on metformin monotherapy in the real world. We analyzed monitoring, treatments and outcomes for such patients using the PHARMetrics® linked laboratory database. **METHODS:** An algorithm based on ICD-9 codes and laboratory test values identified 1901 T2DM patients who failed metformin monotherapy between 2000 and 2006. The index date was defined as the first Hba1c test greater than the ADA recommended goal of 7%, after at least 6 months metformin monotherapy. The pre-period was defined as two years prior to the index date. The follow-up period was defined as 12 months after the index date. Other laboratory test values were obtained during a +/–30-day window of the index date. Micro- and macrovascular diabetes-related complications were identified using ICD-9 codes during the pre-period. Subsequent glucose control and first therapy change in the 3 to 12 months of the follow-up period were also analyzed. **RESULTS:** A total of 48.5% of the sample was male. Mean age was 57.9 (±11). The prevalence of diabetic-related complications were as follows: retinopathy (12.64%); neuropathy (12.13%); nephropathy (2.67%); myocardial infarction (1.31%); stroke (2.82%) and ischemic heart disease (12.99%). In the follow-up period, 76.5% of patients had an Hba1c test and only 24.7% were at goal. Only 33% changed therapy: 19% added on sulfonylurea; 5% switched to a fixed-dose combination product and 4% added or switched to thiazolidinedione. Overall, the average time from failure until therapy change was 256.0 days (±73.1). **CONCLUSION:** These results indicate considerable unmet medical need in treating T2DM. Glycemic control would have likely been better with additional pharmaceutical utilization.

DRUG USE RESEARCH I

DU1

DEMOGRAPHIC RISK FACTORS FOR STROKE RELATED AMBULATORY CARE UTILIZATION: ANALYSIS OF UNITED STATES NATIONAL DATA 2000–2005

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OBJECTIVE: To assess age, racial, and regional differences in utilization of physician, hospital outpatient and emergency department services related to stroke over the past six years. **METHODS:** This study was a retrospective analysis of the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) from 2000–2005. Ischemic stroke related visits in persons aged ≥45 years were identified using diagnosis codes (ICD 9 CM) 433.1x, 434.xx, and 436.xx. Visits per/1000 persons were calculated using United States population estimates. With logistic regression, we adjusted associations between stroke-related visits and age, race, and region (Northeast, Midwest, West, and South), for sex, stroke risk factors, insurance type, and survey year. **RESULTS:** From 2000 to 2005, stroke-related ambulatory care visits increased significantly from 8.3/1000 persons to 16.1/1000 persons (P Trend=<0.0001)–Crepresenting a 195% rise in stroke