## Abstracts

included. The index date was chosen such that each patient had at least 6 month's treatment with either of the products-before and at least 6 months after that date. Patients receiving other oral anti-diabetic drugs were excluded. To compensate for lack of double-blind randomization and to reduce selection bias, patients in the pioglitazone group were matched 1:1 with the insulin group based on propensity score calculated using demographic characteristics, co-morbidities, medical therapies, duration of diabetes, and duration of treatment. The odds ratio for the microvascular event in the follow-up period was determined using logistic regression with treatment as a factor and significant (p < 0.1) baseline characteristics as covariates in the model. **RESULTS:** A total of 453 patients in the pioglitazone group were matched to 453 patients in the insulin group. The crude event rate in the pioglitazone group was 3.09% compared with 9.49% in the insulin group (p < 0.001) and the odds ratio was 0.304 for pioglitazone (95% CI = 0.164, 0.564; p < 0.001). The significant risk reduction projected for the pioglitazone group could not be completely explained by baseline laboratory measurements of lipids, serum creatinine, blood pressures, or duration of diabetes. CONCLUSION: In this retrospective, propensity-matched analysis in patients with type-2 diabetes, the pioglitazone-treated group was associated with a significantly lower incidence of microvascular events than the insulin-treated group.

## COMPARISON OF PIOGLITAZONE WITH OTHER ANTIDIABETIC DRUGS FOR ASSOCIATED INCIDENCE OF LIVER FAILURE: NO EVIDENCE OF INCREASED LIVER FAILURE WITH PIOGLITAZONE

PDB2

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Takeda Pharmaceuticals North America Inc, Lincolnshire, IL, USA **OBJECTIVE:** To assess the incidence of liver failure in association with anti-diabetic treatment using pioglitazone versus other oral anti-diabetic medications. METHODS: The study was a retrospective analysis of claims data from the PharMetrics Patient-Centric Database that had over 1.12 million enrollees with type 2 diabetes. All patients ≥18 years of age with type 2 diabetes who had initiated treatment with either a thiazolidinedione (pioglitazone and rosiglitazone), sulfonylurea, or metformin were identified and matched on the basis of propensity scores, which served as a proxy for severity of disease. The primary measure of interest was the incidence of liver failure or hepatitis post-index date. In addition to unadjusted comparisons, Cox proportional hazards models were employed to estimate the risk of developing liver failure or hepatitis. RESULTS: There was no significant difference in the 1-year and 2-year incidence rates of liver failure or hepatitis (primary and secondary diagnosis) between the pioglitazone monotherapy group and respective comparator groups (pairs matched with rosiglitazone, n = 1847(p > 0.808); with sulforylurea, n = 1474 (p > 0.219); and with metformin, n = 1137 (p > 0.284)). Cox proportional hazards models controlling for age, pre-index total health care costs, charlson comorbidity index, procedures and a hospitalization or ER visit for pre-index hyperglycemia echoed these results. Further, no primary or secondary diagnosis of liver failure was reported in the pioglitazone group during the follow-up period. CONCLUSION: Results of retrospective data analysis using the PharMetrics cohort of patients with type 2 diabetes demonstrate that there is no evidence of increased risk of liver failure or hepatitis for patients initiating therapy on pioglitazone compared to other oral anti-diabetic agents. Pioglitazone therapy was not associated with an increased risk of liver failure at 2 years relative to other oral anti-diabetic therapies.

PDB3

PDB4

## EVALUATION OF PHARMACIST INTERVENTIONS IN DIABETIC PATIENTS FROM RURAL COMMUNITY HEALTH CENTERS

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**OBJECTIVES:** The project focuses on improving the drug use process in the management of patients with chronic diseases, especially diabetes. This HRSA funded program includes education and training of pharmacists in five community health centers about specific disease state therapies, monitoring, and management. The study hypotheses are: 1) patients exposed to the intervention will have improved medical and patient outcomes based on changes in HbA1c, diabetes symptoms, LDL, blood pressure, and health related quality-of-life, and 2) process measures consistent with best practices will improve for patients exposed to the intervention. METHODS: The project uses a prospective design to determine whether exposure to the intervention over two years leads to improved outcomes and processes of care. Patients are the unit-of analysis and serve as their own controls. Subjects include adults with Type 2 Diabetes Mellitus and HbA1c >8 mg/dL within a 3-month period of enrollment. Subjects meeting the inclusion criteria are consecutively drawn from a subset of clinic patients. Medical outcome data are collected from medical and laboratory records, pharmacy records and patient self-report. Study measures include clinical indicators, quality-of-life, satisfaction and HEDIS diabetes-related process measures. Outcomes and process data is collected at baseline and every six months. RESULTS: Of the 142 patients enrolled in the study, 137 are at the 6-month level and 104 are at the 12-month level. The means at baseline for HbA1c, lipids and blood pressure were 9.45, 122.54 (LDL), 136.63 (systolic) and 80.70 (diastolic) while the six-month means were 8.53, 110.74, 135.16, 79.59 respectively. Wilcoxon Sign-Ranked test indicated significant differences in HbA1c and LDL mean values (p <= 0.000 &  $p \ll 0.10$  respectively). However, the differences were nonsignificant for blood pressure values. CONCLUSIONS: The baseline and 6 month values of these clinical markers indicate an improvement in diabetes health outcomes for the patients included in this initiative. Early findings support a positive impact of pharmaceutical care on diabetes outcomes.

## PARTICIPATION IN HOME-BASED AIC TESTING IN CAREPATTERNS® PROGRAM FOR DIABETES

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**OBJECTIVES:** Even though guidelines suggest glycosylated hemoglobin A1c (HbA1c) testing at least twice a year for diabetics and despite the correlation between long term glycemic control and reductions in overall health care costs and service utilization, studies have estimated that only 75% of diabetes patients receive annual HbA1c screening. The purpose of this study was to examine the relationship between participation in a free HbA1c home-testing program and several individualspecific variables, including age level, gender, income range and disease severity. METHODS: Participants enrolling in the CarePatterns® Disease Management Program for Diabetes from January 1, 2003 through June 30, 2003 and who opted to participate in the free home-based HbA1c testing program were included in the study. Allowing sufficient time for test completion and return, Chi-squared (c2) and Cochran-Mantel-Hanzel (CMH) statistics were utilized to examine the relationship between home-testing participation and the independent