DIABETES—Clinical Outcomes/Healthcare Policy

PDB1

RELATION BETWEEN MEDICATION COMPLIANCE AND GLUCOSE CONTROL IN PATIENTS WITH TYPE 2 DIABETES

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OBJECTIVES: To determine whether diabetes patients who are more compliant with their medication therapy tend to have a better glucose control. **METHODS:** The analysis is based on clinical and survey data of 301 patients from 6 clinical centers in different regions of the U.S. Medication compliance is quantified from the Morisky score, and the A1c fraction of glycosylated hemoglobin (HbA1c) from a recent lab test is used to measure glucose control. The relation between the two is established with a general linear model controlling for a set of covariates. The covariates include diabetes severity proxies (the number of anti-diabetic agents, insulin vs. non-insulin regimen, diabetes complications), length of time with diabetes, demographic factors (age, gender, ethnicity), body mass index score (BMI), education level, payment source, and clinic site. **RESULTS:** About 70% of the diabetes patients in the sample were considered compliant (Morisky score of 3 or greater). Compliance patients had an HbA1c score 10% better or lower than non-compliant patients, adjusted for covariates ($p = 0.0003$). As a by-product of the analysis, each additional anti-diabetes medication was seen to be associated with 3.6% increase in HbA1c score. **CONCLUSIONS:** Self-reported compliance with anti-diabetic medications appears to be related to HbA1c. Future research should correlate self-reported compliance with pharmacy claims, and should be expanded to a different sample.

PDB2

IMPROVEMENT OF HEMOGLOBIN A1C (HBA1C) TESTING AND ANALYSIS OF PARTICIPANT-REPORTED RESULTS IN CAREPATTERNS® FOR DIABETES PROGRAM

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OBJECTIVES: HbAlc is considered a cornerstone of diabetic care, a recognized clinical measure within diabetes disease management and an important tool to help patients assess their own diabetes management. This study examines the frequency of participant-reported HbAlc testing and improvement of results after the Carepatterns® intervention. **METHODS:** Study participants enrolled in the program and were enrolled continuously for at least 1 calendar year beginning in 2000. They were asked if they received the Alc test from their physician during their initial and annual telephonic assessment calls. The result of the test was collected if available. If the participant did not receive the test or did not know if they had, they were educated on its importance. Participants were encouraged to ask their doctor about testing and to discuss their results. Data were compiled and a 95% confidence interval and corresponding p-value was computed from the formula for the difference between 2 independent proportions and paired t-tests. **RESULTS:** Of 4257 study participants, 69% initially reported receiving an HbAlc test, and 83% at annual for a D 14%, (95% CI 12%-16%, $p < 0.05$). An analysis of 373 participant reported test values was performed using a matched paired-t test when the value of the test was provided during initial and annual assessment. At initial assessment, mean test result of 7.02% was reported and during their annual call, 6.76%. The mean change 0.26 (95% CI 0.16 to 0.37 $p < .05$) was significant. **CONCLUSIONS:** These findings show that CarePatterns® for diabetes program enrollees are improving their compliance with the HbA1c test as well as lowering their participant-reported test values after participating in the program.

PDB3

EFFICACY OF INSULIN GLARGINE IN PATIENTS WITH TYPE 1 AND 2 DIABETES

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OBJECTIVES: Insulin glargine is a biosynthetic insulin analog with a prolonged duration of action. Our objective is to determine the efficacy of insulin glargine regarding glycemic control in patients with Type 1 and 2 diabetes. A secondary objective is to determine potential cost savings, if any, that may result from the use of insulin glargine as an alternative to oral hypoglycemic agents in patients with Type 2 diabetes. **METHODS:** A total of 135 patients with a diagnosis of Type 1 or 2 diabetes initiated on insulin glargine by institutional endocrinologists from April 2001 to September 2001 were included in this study. Medical and pharmacy claims databases were retrospectively analyzed 1 year pre- to 1 year post-initiation of insulin glargine. Hemoglobin A1c (HbA1c), frequency of hypoglycemic adverse events, and utilization of oral hypoglycemic agents were evaluated. **RESULTS:** Average HbA1c significantly decreased by 0.31% from 8.48% pre-glargine to 8.16% post-glargine ($P = 0.012$). The overall frequency of hypoglycemia and nonsevere hypoglycemia were both significantly lower in the post-glargine period (69% vs. 36%, $P < 0.001$ and 38% vs. 19%, $P < 0.01$, respectively). In patients with Type 2 diabetes, a trend toward decreased utilization of oral hypoglycemic agents in the post-glargine period was observed in the sulfonylureas, thiazoladinediones, and biguanides (58.5% vs. 39%, $P < 0.01$). The use of insulin glargine as an alternative to oral hypoglycemic agents resulted in

a cost savings of $21,200 per year in 41 patients with Type 2 diabetes. **CONCLUSION:** Control of diabetes as measured by the HbA1c was significantly better after the initiation of insulin glargine with benefits including a decreased overall frequency of hypoglycemia. Additionally, insulin glargine may be a cost-effective alternative to increases in the dose or number of oral hypoglycemic agents in patients with Type 2 diabetes. Conclusive evidence on the efficacy of insulin glargine will come from larger cohort studies.

PDB4

OBTAINING QUALITY REAL-WORLD TREATMENT DATA FOR ECONOMIC MODELS: METHODOLOGY AND RESULTS OF A WOUND CARE MEDICAL RECORD ABSTRACTION STUDY

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OBJECTIVES: Although clinical trial data are often used in economic models, they may not reflect real-world utilization and outcomes of therapy. To determine real-world resource use and outcomes of diabetic foot ulcer (DFU) care using Graftskin (a living bi-layered skin substitute) and to supplement clinical data for a DFU treatment model, a medical record abstraction study was conducted at 21 U.S. treatment centers that practice good wound care (GWC). **METHODS:** Two physician samples were recruited: a Graftskin sample (physicians who frequently use and receive reimbursement for Graftskin in the treatment of DFUs), and a non-Graftskin sample (physicians who treat DFU using GWC and who do not receive reimbursement for using Graftskin). Separate abstraction forms were developed for each sample, sent by mail to the treatment centers, completed by center staff, and returned via fax. The center received a small honorarium per completed form. **RESULTS:** Twenty-one centers and 166 cases (83 Graftskin and 83 GWC) were included in the analysis. Graftskin patients had more severe DFUs (21 cm^2) than those in the Graftskin pivotal trial (2.97 cm^2), which compared GWC plus Graftskin to GWC alone. In addition, Graftskin patients had more severe DFUs than the GWC patients in this study (11 cm^2). The mean number of Graftskin applications was much lower in this study (1.27 applications) than in the Graftskin pivotal trial (3.9 applications). Moreover, in this study, the incidence of severe adverse events was significantly lower with Graftskin (37%) than with GWC (52%), even when controlling for ulcer severity ($p = 0.006$). **CONCLUSION:** In actual practice, the number of Graftskin applications was considerably lower and DFU severity was substantially higher than in the Graftskin pivotal clinical trial. These data were applied to the DFU treatment model, which yielded improved estimates of the real-world impact of utilizing Graftskin versus GWC.

PDB5

MEDICATION COMPLIANCE IN TYPE 2 DIABETES SUBJECTS: RETROSPECTIVE DATA ANALYSIS

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OBJECTIVES: Medication adherence and compliance are problems in young and elderly patients. With the increasing number of prescribed drugs, compliance drops and the number of adverse events increases. Furthermore, elderly patients are likely to have several co-morbidities, which could also affect their drug-consumption behavior considerably. In this study, our objective was to evaluate the compliance of anti-diabetic medication therapy in subjects with type 2 diabetes mellitus who initiated treatment with one of various oral anti-diabetic drugs or insulin. **METHODS:** Data for this study spanned the period January 1, 1995 to March 31, 2002 and were obtained from the Pharmetrics Patient-Centric Database, which is comprised of fully adjudicated medical and pharmaceutical claims for over 29 million unique patients from 52 health plans across the US. Patients with Type 2 diabetes mellitus (n = 199,000) were classified into mutually exclusive treatment groups based on the therapy first received during the period of observation. Compliance rate was determined by the total number of days between first filled and last filled prescription plus days filled in the last prescription, divided by last fill date and the first fill date plus a 90-day gap. **RESULTS:** The pioglitazone group (n = 2,730) ranked the highest in compliance with a mean of 85% (89% in the 55–64 age group) and a median of 91% compared to a mean compliance of 62% in the insulin group (n = 27,274) ($P < 0.001$) and 81% in the metformin group (n = 52,469) ($P = 0.001$). Similar results were found in newly diagnosed subjects. One-third of all pioglitazone patients added a second line therapy for diabetes compared to 43.9% on rosiglitazone (n = 4,068). **CONCLUSION:** Compliance to treatment regimen for patients taking pioglitazone was higher than for patients on other anti-diabetic medications.

PDB6

FACTORS ASSOCIATED WITH HIGH-RISK DIABETIC PATIENTS IN THE CALIFORNIA MEDICAID POPULATIONS (MEDI-CAL)

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OBJECTIVES: Patient risk is identified by an increase in healthcare cost, the occurrence of hospitalization or emergency room (ER) event, and a decrease in time to hospitalization or ER event. The purpose of this research is to investigate factors associated with high-risk diabetic patients based on claims data from the California Med-