

Project Number: IIR 10-136-2

Project Title: Comparative Effectiveness of Anti-diabetic Medication Alternatives for Veterans

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**Objective(s):**

Twenty percent of VA users are estimated to have Type 2 diabetes. In the VA, metformin is commonly used as first line therapy and the usual recommended second-line agent is a member of the sulfonylurea class. Despite the availability and function of these two classes of medication, over half of VA patients with diabetes require further blood sugar lowering medication beyond metformin and sulfonylurea (MET-SU). The two most common drug classes used for patients not achieving adequate glycemic control on MET-SU are thiazolidinediones (TZDs), short- and long-acting insulin, insulin analogues, and human insulin. Unfortunately, there are few data comparing the effectiveness of various medications available for use at this treatment transition. This project aims to describe the variation in glucose lowering medication prescribing patterns throughout the VA in patients who transition from MET-SU to additional treatments. We will develop a statistical model that predicts variation in glucose lowering medication prescribing patterns. In addition, we will estimate the relationship between anti-diabetic medication prescribing patterns and short and longer-term health outcomes.

**Research design:**

This retrospective study of secondary data will capitalize on variation in practice patterns to examine which diabetes medications are most effective in patients as their glucose control deteriorates over time. Multiple patient-level administrative data sets from the VA, Medicare and Medicaid will be combined with public use data sets to get a comprehensive view of prescribing practice patterns and short- and long-term health outcomes between January 1<sup>st</sup>, 2000 and December 31<sup>st</sup>, 2010.

**Methods:**

This study will examine the causal relationship between prescribing patterns and risk-adjusted health outcomes using a unique national sample of VA patients diagnosed with diabetes (between January 1<sup>st</sup>, 2000 and December 31<sup>st</sup>, 2005) and instrumental variables analysis. The criteria for identifying diabetes will be a prescription for anti-diabetes medication in the current year and/or 2+ diabetes codes for inpatient and/or outpatient visits over a two month period. We will require that all patients in the cohort have a medication history that includes both MET-SU and that they add at least one TZD or type of insulin at some point during the study. For risk adjustment and outcomes we will limit the cohort to individuals who are low-income and eligible for Medicare. We will follow all individuals through 2010, but will not add new patients to the cohort after 2005.

Findings: N/A

Clinical relationships: N/A

**Impact/Significance:**

This study is designed to inform the VA formulary treatment of TZDs and insulin analogues, directly affecting VA patients' access and exposure to these medications. Beyond formulary policy, local Pharmacy and Therapeutics (P&T) committees establish procedures to manage access to non-formulary medications. If this project finds evidence that TZDs or insulin analogues are more or less effective than alternatives, this information could be used in the non-formulary request process. The results of this study will also be of interest to VA clinicians who need to assess the risks and benefits of the anti-diabetic medications for each patient and specific patient subgroups.