Real-world evidence adds value.

**Diabetes treatment landscape**

The market for diabetes treatment is one of the most saturated, with several clinically effective treatments available to help patients achieve glucose goals. While there are numerous clinical trials comparing diabetes drugs with placebos, there is relatively little in the scientific literature comparing two or more treatments or therapeutic classes head-to-head. Administrative claims data have the capacity to address this knowledge gap.

The Optum® Research Database (ORD) is comprised of over 60 million unique patient lives going back to 1993. The ORD contains linked administrative pharmacy and medical claims data, enrollment information, and laboratory results for commercial and Medicare Advantage beneficiaries across the United States. These data have proven to be a rich source for real-world investigations across the health care spectrum. The Optum Health Economic and Outcomes Research (HEOR) team has published over 100 peer-reviewed publications in the diabetes research arena alone.

**Highlights of our HEOR team’s contributions in the following areas of diabetes research are presented here:**

- Treatment patterns in patients with diabetes
- Glucose control
- Comorbid conditions
Real-world evidence in diabetes

Treatment patterns

Real-world comparison of two GLP1 receptor agonists

The objective of this study was to compare two glucagon-like peptide-1 (GLP1) receptor agonists in a real-world setting. Included were adult patients with type 2 diabetes initiating treatment with either albiglutide or liraglutide in the Optum Research Database administrative claims and linked laboratory test results. Propensity score matching was used to minimize confounding bias when estimating the effect of treatment. Treatment patterns and HbA1c were measured in the follow-up periods. Over six months follow-up, adherence was significantly higher in the albiglutide cohort compared with the liraglutide cohort. Patients initiating albiglutide had higher mean proportion days covered, longer persistence and lower likelihood of discontinuation. With regard to glucose control, the mean change in HbA1c was similar in both cohorts.

Patients initiating injectable therapy

Treatment intensification is necessary in patients unable to achieve glycemic control on first-line oral therapy alone. Injectable therapies, such as basal insulin and GLP1 receptor agonists, are usually second-tier therapies. This large study aimed to provide better understanding of prescribing and treatment patterns in a real-world setting. Important clinical differences in patients initiating treatment with insulin glargine and GLP1 agonists were observed. Insulin glargine patients had significantly higher HbA1c at baseline, as well as higher Charlson comorbidity index scores, while patients initiating GLP1s had lower body weight and lower diabetes-related costs in the baseline period. These results suggest that prescribing patterns vary by patient characteristics. These findings illustrate the challenges in translating clinical trial results to the real world, highlighting the need for real-world studies.

Adherence in patients switching from monotherapy or dual therapy

Amid concern that multiple medication regimens can lead to poor medication adherence and, as a result, poor glycemic control, this study sought to examine the impact of combining two or more medications in a single administration (fixed-dose combination therapy) on treatment adherence and outcomes. This study assessed changes in adherence associated with switching from rosiglitazone or sulfonylurea to rosiglitazone/glimepiride fixed-dose combination therapy or loose-pill combination therapy in adult patients with type 2 diabetes mellitus. Patients switching from monotherapy to fixed-dose combination therapy had smaller reduction in medication possession ratio compared with those switching to loose-pill combination therapy. Patients switching from loose-pill dual therapy to fixed-dose combination therapy had increases in medication possession ratio and larger decreases in HbA1c compared with those who remained on dual therapy.
Glucose control

Characteristics and outcomes of patients initiating treatment with an SGLT2 inhibitor

This study employed the ORD to evaluate outcomes associated with use of canagliflozin in a real-world setting. Adult patients with type 2 diabetes with pharmacy claims for canagliflozin between April 1, 2013, and October 30, 2013, were included (the first seven months canagliflozin was available). At the time of canagliflozin treatment initiation, 20 percent were not on any other antidiabetic agents, 30 percent were initiating canagliflozin as second-line treatment, and the remaining 50 percent were already on combination therapy. Over six months follow-up, mean HbA1c reduction was 0.81 percent. Approximately 20 percent of patients on combination therapy at canagliflozin treatment initiation discontinued one or more antidiabetic agents in the follow-up period. 5

Glycemic control among patients treated with an SGLT2 inhibitor or DPP4 inhibitor

The aim of this analysis was to evaluate glycemic control (HbA1c) in patients with type 2 diabetes mellitus treated with the sodium-glucose co-transporter-2 (SGLT2) inhibitor canagliflozin or a dipeptidyl peptidase-4 (DPP4) inhibitor. This study used medical and pharmacy claims, enrollment information, and linked laboratory results from the Optum Research Database. Adult patients with type 2 diabetes mellitus initiating treatment with either canagliflozin or a DPP4 inhibitor were identified and matched on HbA1c ≥/≤7% and propensity score. Patients in the canagliflozin cohort exhibited larger reductions in HbA1c and were more likely to meet HbA1c goals. 6

Comorbid conditions in patients with type 2 diabetes

Prevalence of renal insufficiency in Medicare patients with type 2 diabetes

The objective of this study was to determine the prevalence of renal insufficiency in Medicare Advantage enrollees with type 2 diabetes mellitus. Renal insufficiency was defined using both a claims-based algorithm and serum creatinine lab results, and National Kidney Foundation five-stage classification. Among patients with lab results, 23.2 percent of the study sample had diagnosis codes indicating renal insufficiency and 80.3 percent had evidence of eGFR-based renal insufficiency. Patients with lab-based renal insufficiency had 42 percent higher diabetes-related total health care costs compared with those without indication of renal insufficiency. 7

Optum Research Database and linkable assets

The ORD has several advantageous features for observational research in diabetes. Claims data offer a complete picture of a patient’s interactions with the health care system. Over 60 million unique patient lives with medical and pharmacy data and an average of 31 months follow-up, allowing for examination of small population subgroups, such as those initiating treatment with a new drug. Optum is ideally positioned to examine pleiotropic effects of SGLT2 and GLP1 therapies on renal, hepatic, and cardiovascular outcomes in patients with T2DM. In addition, the ORD can be linked to other Optum data assets, including:

- Laboratory results
- Electronic health records (EHR) clinical data
- Socio-demographic data
- Ability to identify patients for direct-to-patient surveys
- Ability to identify providers for provider surveys
Real-world evidence in diabetes


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