

A New United States Database for Pharmacoepidemiology Studies in Type 2 Diabetes Mellitus: the IMEDS Distributed Database

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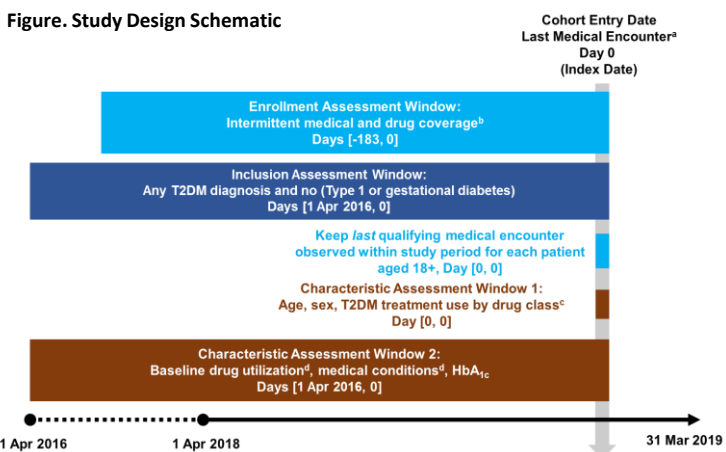
Background

- The Innovation in Medical Evidence Development and Surveillance System Distributed Database (IMEDS-DD) is a subset of the Food and Drug Administration's Sentinel Distributed Database¹, a national system for active surveillance of medical product safety in the United States
- Standardized using the Sentinel Common Data Model², the IMEDS-DD aggregates healthcare claims data up to 111 million member-lives across 9 health plan partners and is compatible with the Sentinel's parameterizable analytic tools³ for rapid queries. Specific data elements include health plan enrollment, demographics, pharmacy dispensings, and clinical diagnoses and procedures
- The IMEDS-DD has not yet been used to evaluate patients with type 2 diabetes (T2DM)

Objectives

- To assess data relevancy and data quality of the IMEDS-DD for diabetes research
- To evaluate comparability of the IMEDS-DD T2DM cohort to the general population with T2DM

Figure. Study Design Schematic



- Cohort entry date was defined by date of the last medical encounter during the period from 4/1/2018 to 3/31/2019. Members were only allowed to enter the analytic cohort once
- Health plan enrollment might start before 4/1/2018. Up to 45-day gap(s) in medical or prescription drug plan enrollment was allowed
- Evidenced by dispensing date or days supply (indicator of ongoing drug use)
- Drug utilization defined via outpatient pharmacy dispensings and National Drug Codes. Existing conditions defined using standardized diagnosis and procedure codes recorded in medical encounter claims

Results

Availability of key data elements in the IMEDS-DD for diabetes research (Table)

- T2DM prevalence was 12.6% in the IMEDS-DD
- Of 414,672 identified patients with T2DM, 52.8% were male and 24.1% were over 75 years of age (mean 65.0, SD 13.3) years
- Common comorbid conditions included hypertension (84.5%), hyperlipidemia (82.8%), obesity (45.3%), cardiovascular disease (44.7%), and moderate-to-severe chronic kidney disease (20.2%)
- Ongoing antihyperglycemic agent (AHA) dispensings as of the index date included metformin (35.7%), sulfonylureas (14.8%), and insulin (9.9%)
- 48.9% patients with T2DM had 1 or more HbA_{1c} value recorded. The mean of the most recent value was 7.0% (SD 3.2%), and 11.0% of these results were 9.0% or higher

Comparability of the IMEDS-DD T2DM population to the general T2DM population

- Comparable T2DM prevalence to national prevalence established by the Centers for Disease Control and Prevention (CDC, 13.0%)⁴
- Comparable demographics and comorbidities to estimates from the CDC⁴ and those reported for patients with T2DM identified in other large health care databases previously used for diabetes research⁴⁻¹⁶ such as the National Health and Nutrition Examination Survey (NHANES), the IBM MarketScan Research Databases, and the Quintiles Electronic Medical Record research database (Q-EMR)
- Comparable AHA treatment patterns to those reported for patients with a T2DM diagnosis^{7,17}, despite generally lower utilization than those observed for patients identified with a T2DM diagnosis and/or an oral AHA¹⁴
- Consistent HbA_{1c} findings with other observational studies using claims databases, where clinical parameters such as HbA_{1c} was mostly missing or not captured from insurance claims¹⁸⁻²⁰

Conclusions

- The IMEDS-DD contains key data elements to conduct pharmacoepidemiologic studies in patients with T2DM, including demographics, clinical characteristics, and health services utilization
- The IMEDS-DD contains comparable data on the characteristics of patients with T2DM to those found in other large databases

Institute Review Board determination: Review exempted determined by IMEDS Analytic Center at the Harvard Pilgrim Health Care Institute

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Methods

- A retrospective study was conducted using the IMEDS-DD comprising administrative and claims data from 7 national and regional health insurers in the US who agreed to participate in the study
- Study period: 1 April 2016 to 31 March 2019
- Index period: 1 April 2018 to 31 March 2019, during which eligible members must be 18 years or older and have 1 or more medical encounter as well as 6 months of or longer medical plus prescription drug use history available
- T2DM (defined as 1 or more diagnosis of T2DM and no diagnosis of type 1 or gestational diabetes), comorbid conditions, and hemoglobin A_{1c} (HbA_{1c}) were determined using all data available from 1 April 2016 to the most recent encounter (index date)
- Patient characteristics, comorbidities, and HbA_{1c} values were summarized and compared to those of the general T2DM population established in national benchmarks and in the literature

Table. Characteristics of Type 2 Diabetes Mellitus (T2DM) Patients Identified in the IMEDS-DD

	n/Mean	%/SD
Number of patients with T2DM	414 672	100.0%
Demographics		
Age, years	65.0	13.3
18-44	35 361	8.5%
45-64	168 013	40.5%
65-74	111 366	26.9%
≥ 75	99 932	24.1%
Sex: male	218 759	52.8%
Comorbid conditions		
Combined comorbidity score ²¹	3.6	4.0
Cardiovascular disease	185 527	44.7%
Cerebrovascular disease	72 350	17.4%
Coronary heart disease	129 293	31.2%
Heart failure	70 105	16.9%
Myocardial infarction	48 488	11.7%
Peripheral artery disease	75 018	18.1%
Stroke	63 489	15.3%
Hypertension	350 295	84.5%
Hyperlipidemia	343 350	82.8%
Hypoglycemia	19 579	4.7%
Obesity	187 841	45.3%
Pancreatitis	7 092	1.7%
Moderate to severe renal impairment	83 653	20.2%
Diabetic complications	197 853	47.7%
Nephropathy	131 991	31.8%
Neuropathy	105 188	25.4%
Retinopathy	45 380	10.9%
Amputation	2 976	0.7%
Use of antihyperglycemic agents at the index date		
Metformin	147 954	35.7%
Insulin	41 148	9.9%
Sulfonylureas	61 395	14.8%
Thiazolidinediones	10 426	2.5%
SGLT2 inhibitors	16 231	3.9%
DPP-4 inhibitors	24 797	6.0%
GLP-1 agonists	16 366	3.9%
Others (alpha-glucosidase inhibitors, meglitinides)	1 431	0.3%
Most Recent HbA_{1c} Test Result*		
No HbA _{1c} test results	212 049	51.1%
HbA _{1c} test result, %	7.0	3.2
< 7.0	129 071	63.7% [†]
7.0-7.9	34 617	17.1% [†]
8.0-8.9	16 660	8.2% [†]
≥ 9.0	22 275	11.0% [†]

*Data from five data partners with HbA_{1c} values available. [†]Percentage calculated from patients with most recent HbA_{1c} results. SGLT2: sodium-glucose cotransporter-2. DPP-4: dipeptidyl peptidase-4. GLP-1: glucagon-like peptide-1.

Limitations: As with any other administrative claims database, the IMEDS-DD provides comprehensive and longitudinal records of encounters with the health care system and of pharmacy dispensings. Yet, the IMEDS-DD also shares general limitations of these databases as follows:

- Possible misclassification due to the use of diagnosis, procedure, and drug codes for identification of medical conditions or drug exposure. For example, rule-out diagnoses are possible and may partially explain the low AHA use among IMEDS-DD T2DM population, as the study might include prediabetes patients with lower HbA_{1c} who did not need AHAs
- Limited clinical details available to verify personal history and severity of the measured medical conditions (while the performance of a lab test, such as HbA_{1c}, would generate a claim, the test result is not always available)
- Most data reflected the use of covered health services only
- Study results are only generalizable to the commercial health insurance population from which the study population was derived as well as other populations sharing similar characteristics

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