Differentiation of adults with type 1 versus type 2 diabetes in administrative claims analysis: experience from the Biologics and Biosimilars Collective Intelligence Consortium

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INTRODUCTION

The Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) was convened by the Academy of Managed Care Pharmacy (AMCP) in 2015 to provide real-world, post-marketed evidence generation for originator biologics and corresponding biosimilars in the US.[1,2]

BBCIC leverages the FDA Sentinel system data and analytic infrastructure: BBCIC Distributed Research Network (DRN). The BBCIC DRN uses the Sentinel Common Data Model (SCDM) for data standardization and Sentinel-based analytic tools for distributed analyses and examining medical product risk and benefit.[3]

Four BBCIC workgroups formed to describe the population cohorts and utilization patterns of biologics with a soon-to-be FDA-approved biosimilars. Herein, we describe the experience obtained from the Insulins Workgroup, whose purpose was to learn about the real-world data (RWD) in the BBCIC DRN.

Initial BBCIC analysis found a significant number of patients with both Type 1 (T1DM) or Type 2 (T2DM) medical claims and excluded these patients due to presence of both diabetic types in claims.[4] Diabetes research does not describe the phenomena or methods to handle the patient with claims for both Type 1 and Type 2 diabetes (T1DM+T2DM) in administrative data. Algorithms that exist use medical chart information that may not be available in the SCDM.[5,6,7]

This analysis describes the paradoxical presence of patients with T1DM+T2DM and compares T1DM+T2DM to single diagnosis type patients. The objective is to characterize T1DM+T2DM patients and determine data available within the BBCIC DRN to differentiate T1DM and T2DM.

METHODS

Data. This retrospective, observational study evaluated two datasets: 1) BBCIC DRN and 2) a sub-set of one BBCIC Data Partner Enterprise Data Warehouse (DP EDW). Both datasets examined patients with either Commercial or Medicare-Advantage health insurance and prevalent T1DM or T2DM .

BBCIC DRN identified adults and medical and drug health plan coverage from **January 1, 2011 through December 31, 2017**. The BBCIC insulin eligible study population criteria included health plan members 18 years or older, with at least one drug claim for long- or intermediate-acting insulin.

DP EDW identified patients with any T1DM or T2DM diagnoses and medical and drug health plan coverage from **January 1, 2016 through June 30, 2018**. T1DM or T2DM diagnoses and oral anti-diabetic (OAD) drug dispensings were counted in the 30-month period. The DP EDW allowed investigation of T1DM differentiation algorithms prior to use in the full BBCIC DRN.

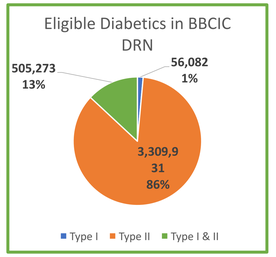
Patients with diabetes was the **unit of analysis.** Insulin episodes were defined in the initial BBCIC analysis.[4] The percentage of T1DM diagnoses in medical claims (T1DM_PCT) was only calculated on patients with both T1DM+T2DM in the DP EDW.

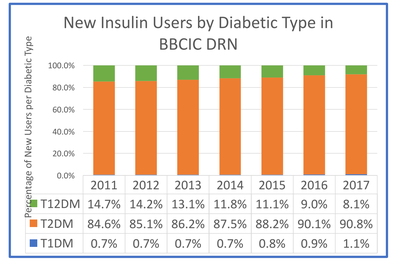
Descriptive analysis of diabetic type cohorts included counts, percentages, and means and the percentage of T1DM diagnoses for T1DM + T2DM patients. Data is presented by 3 diabetic types: 1) T1DM 2) T2DM 3) T1DM +T2DM.

Algorithms. Three peer-reviewed publications describing T1DM algorithms were reviewed. The algorithm variables were compared to the SCDM.

RESULTS

There were 3,871,286 eligible adults with diabetes in the BBCIC DRN. Of those, 56,082 (1%) had a T1DM diagnosis, 3,309,931 (85%) had a T2DM diagnosis, and 505,273 (13%) had both T1DM+T2DM diagnoses. The number and percentage of T1DM+T2DM adults with diabetes and new insulin users declined 2011 through 2017, while the number of adults with only T1DM or T2DM claims increased. The age distribution and the average number of episodes of T1DM+T2DM and T2DM patients were similar. Over 35% of T1DM are over the age of 50.





	2011	2012	2013	2014	2015	2016	2017
T2DM	14.7%	14.2%	13.1%	11.8%	11.1%	9.0%	8.1%
T2DM	84.6%	85.1%	86.2%	87.5%	88.2%	90.1%	90.8%
T1DM	0.7%	0.7%	0.7%	0.7%	0.8%	0.9%	1.1%

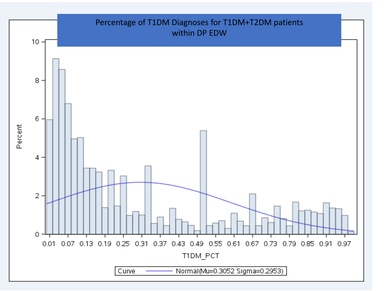
New Users Demographics by Diabetic Type in BBCIC DRN

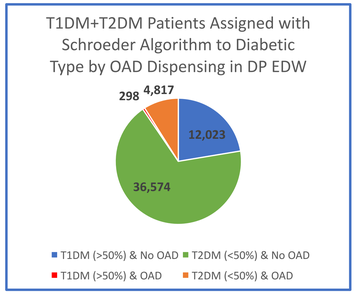
	T1DM		T2DM		T1DM + T2DM	
New insulin users	42,387		2,904,657		444,901	
Females	20,173	48%	1,393,119	48%	207,318	47%
18-49 years	27,088	64%	746,139	26%	123,997	28%
50-64 years	10,586	25%	1,409,318	49%	169,718	38%
65-79 years	3,583	8%	759,456	26%	129,569	29%
80+ years	1,556	4%	222,662	8%	44,368	10%
New Insulin Episodes	89,208		11,276,481		1,382,273	
New Insulin Episodes/ Users Ratio	2.1		3.9		3.1	
Dispensings	218,733		32,866,517		3,838,069	
Dispensings/ Episodes Ratio	2.5		2.9		2.8	

Algorithms identifying T1DM Variable Review

Algorithm	Variables	SCDM Availability Assessment
Klompas[4]	diagnosis codes ICD9: T1DM,T2DM	yes
	RX: glucagon	yes, but limited
	RX: oral hypoglycemic	yes
	c-peptide test value	no
	diabetes autoantibodies test value	no
	RX: urine acetone test strips	yes, but limited
Schroeder[7]	diagnosis codes ICD9/ ICD10: T1DM,T2DM	yes
Lo-Ciganic[5]	diagnosis codes ICD9: T1DM,T2DM, diabetic ketoacidosis	yes
	age	yes
	outpatient RX for insulin and/ or OAD	yes
	inpatient RX for insulin and/or OAD	very limited

T1DM identification algorithms from 3 publications were evaluated for variables within the BBCIC DRN. BBCIC DRN contains ample diagnoses and outpatient pharmacy dispensings, but not prescriptions, necessary lab values, or complete medical histories. The reasons for variable absence include people have multiple health plans in their lifetime; lab values and inpatient dispensings are not included on medical claims; and, health plans receipt of pharmacy dispensings, not prescriptions.





Of 53,712 DP EDW patients with T1DM + T2DM, Shroeder's algorithm percentage of T1DM identified 12,321 (23%) patients with T1DM and 41,391 (77%) patients with T2DM. Of the 5,115 with at least one OAD, 94% patients were identified as T2DM.

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CONCLUSIONS

BBCIC analyzed prevalent insulin users to understand the populations expected to use biosimilars or follow-on biologics. The BBCIC insulin using population had 13% of people with T1DM+T2DM diagnosis codes observed during the study period which accounted for over 50% of insulin users who met the insulin study criteria (clinical exclusions applied). The initial BBCIC analysis excluded these patients; however, with an algorithm to differentiate T1DM and T2DM those patients could be included.

T1DM and T2DM algorithms include clinical elements not available or limited in the BBCIC DRN. With the large proportion of T1DM+T2DM insulin users, it was important to understand the differences between single and dual diagnosed diabetes, compare ICD9 to ICD10, and investigate T1DM algorithms to identify the appropriate diagnosis category for future insulin comparative studies.

Preliminary work to use a published T1DM differentiation algorithm within the BBCIC DRN is underway. There is need to assign a single diagnosis type due to real-world data paradoxes in future insulin originator-biosimilar/follow-on biologic studies.

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