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HEALTHCARE GAPS IN TYPE-2 DIABETES MANAGEMENT: A US PERSPECTIVE

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Abstract:
Type 2 Diabetes Mellitus (T2D) is a widespread epidemic in the United States, affecting over 30 million Americans, with an additional 34% of adults classified as prediabetic. A T2D diagnosis is linked to a 10-year decrease in life expectancy and an added $9,600 in direct medical expenses per patient. Inadequate T2D management can lead to diabetes-related complications, both microvascular (nephropathy, neuropathy, and retinopathy) and macrovascular (heart disease, stroke, and peripheral artery disease). The consequences of poor T2D management are dire, as individuals with T2D are twice as likely to succumb to cardiovascular disease compared to those without T2D. Therefore, effective T2D management necessitates not only diabetes control but also the screening and treatment of diabetes-related complications.

Keywords: Type 2 Diabetes Mellitus (T2D), Prediabetes, Diabetes-related Complications, Cardiovascular Disease, Disease Management

1. Introduction

In the United States (US), Type 2 Diabetes Mellitus (T2D) is an ongoing epidemic with over 30 million Americans estimated to have been diagnosed with T2D while an additional 34% of the US adult population are considered to be prediabetic.[1] In the US, T2D diagnosis is associated with a 10-year drop in life expectancy and an additional $9,600 direct medical cost for each diabetes patient.[2,3] Poor management of T2D can result in diabetesrelated complications, such as microvascular complications (nephropathy, neuropathy, and retinopathy), and macroscopic complications (heart disease, stroke, and peripheral artery disease).[4] The risks of poor management of T2D are severe. For example, people with T2D are twice as likely to die from cardiovascular disease compared to individuals without T2D.[1,5] Thus, a major component of managing diabetes also includes screening for and treating diabetes-related complications.[6]

To avoid worsening of the disease and reduce chances of diabetes-related complications, intensive and careful management of T2D is encouraged by American Diabetes Association (ADA) guidelines.[6] The ADA's Standards of Medical Care in Diabetes provides robust guidelines for adequately treating and managing the T2D and is updated annually with recommendations based on extensive review of clinical diabetes literature, and input from the medical community including the ADA's Professional Practice Committee.[6] The complexity of adequate management of T2D is illustrated by the ADA's Comprehensive Medical Evaluation which serves as guidelines for initial and follow-up diabetes visits.[5] It includes 59 individual processes of care, divided into eight categories: medical history, social history, medications and vaccinations, technology use, screenings, laboratory evaluation, physician examination, and treatment plan.

Based on the ADA standards of care guidelines, adequate care of T2D requires a complex yearly regimen ranging from appropriate prescribing of antihyperglycemics, life-style changes, adequate preventative care measures, screenings, and treatment of diabetes-associated complications.[6] However, despite the strong evidence supporting the guideline recommendations, a previous study by Delevry et al. published in 2020 estimated adherence to ADA guidelines to be about 50%.[7] This topic of failure to adhere to guidelines is often referred to as clinical inertia, therapeutic inertia, or physician inertia, which is a failure to initiate or intensify therapy according to evidence-based

guidelines.[8–10]Similarly, this topic is also referred to as adherence or non-adherence to evidencebased guidelines.[11–13] However, because care which is adherent to evidence-based guidelines should be the gold standard, the current study views the topic from the perspective of inadequate care: care which is not adherent to evidence-based guidelines for T2D patients.

Inadequate care can encompass many individual aspects or processes of care, which can result in severe consequences. One of the most ubiquitous and acute examples of inadequate care is not receiving appropriate medication. For example, failure to initiate or intensify therapy according to evidence-based guidelines is estimated to contribute to up to 80% of heart attacks and strokes.[14] However, inadequate care includes much more than just receiving appropriate medication. Chronic disease patients especially, require a complex and multifaceted regimen. Among the T2D population, examples of inadequate care include Glycosylated Hemoglobin Test (A1c) screening, cholesterol test, and receiving influenza vaccination.

In pursuing a goal of better understanding inadequate care, the objective of the current study was to examine the prevalence and associated characteristics of non-compliance to processes of care specified by the ADA's Comprehensive Medical Evaluation. The current study investigated inadequate care with the goal of providing conceptual results that are understandable and avoid information overload.

2. Methods

2.1 Study Design and Data Source

A retrospective cross-sectional cohort design was employed, utilizing the latest 2018 Medical Expenditure Panel Survey (MEPS) data. MEPS is a national cross-sectional survey of US households that measures healthcare utilization and medical expenditure annually, published by the Agency for Healthcare Research and Quality (AHRQ).[15] Nationally estimated survey weights are calculated by applying sample weights to reflect the sampling methodology and probability of each participant's selection.[16] The study cohort was developed by linking multiple data files: a full year consolidated data file, hospital inpatient stays file, emergency room visits file, outpatient visits file, office-based medical provider visits file, medical conditions file, and a prescribed medicines file.[15] The data files used include data collected throughout 2018.

2.2 Patient Population

Those included in the study were age 18 or older at index date, defined to be January 1, 2018, and were given the diabetes care survey, which is a supplement survey given to all those surveyed by MEPS that were identified as having diabetes.[17] Additionally, only those with diagnosed with T2D were included. A diagnosis of T2D was defined to be individuals who had a diagnosis code for T2D, had self-reported to have been diagnosed with diabetes by a health practitioner, and had at least one prescription of an antihyperglycemic within 182 days of index date. Antihyperglycemics included drug classes metformin, glucagon-like peptide-1 receptor agonist (GLP1RA), sodium/glucose cotransporter 2 (SGLT2i), dipeptidyl peptidase-4 inhibitor (DPP-4i), thiazolidinedione (TZD), sulfonylurea (SU), meglitinides, amylin analogs, alpha-glucosidase inhibitors, and insulin. The drugs were identified using National Drug Code Directory (NDC) and were checked for accuracy and completeness using Multum MediSource Lexicon names, which were also available in the MEPS prescription data file.[18,19] Individuals were excluded if they were not in-scope for MEPS for the entire year. Diagnosis codes were identified using International Classification of Diseases, 10th Revision, Clinical Modification (ICD-10-CM) codes.

Of 30,461 total observations in the initial dataset, 1,968 were given the diabetes care survey supplement. Of those, one was excluded due to being below age 18 at index date, and six were not in MEPS survey scope for the entire year. Of the remaining 1,961, a total of 1,804 were identified as have a diagnosis of T2D. Of the remaining individuals, 1,665 were identified as having filled a prescription for a hyperglycemic medication within first six months of 2018. The final cohort included 1,665 observations, with a nationally estimated total of 22,385,168.

Figure 1. Flowchart of exclusions from the initial Medical Expenditure Panel (MEPS) Survey dataset, among those with type 2 diabetes (T2D).

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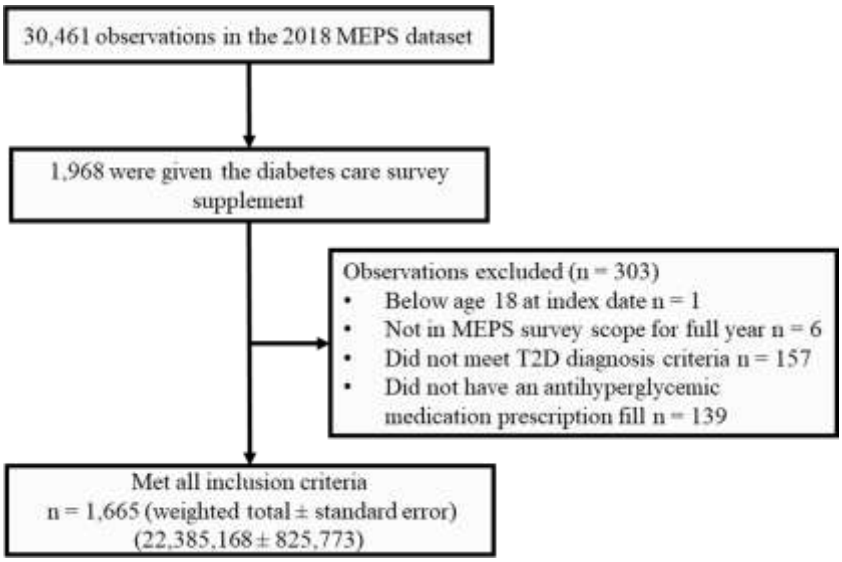

2.3 Outcomes Measures

The primary outcome of interest is the prevalence of inadequate care among the T2D population. Inadequate care was defined in the current study based on the ADA's guidelines for T2D care, which is outlined in their comprehensive medical evaluation and detailed in annually published Standards of Medical Care in Diabetes.[6]Because it is not feasible to look at all 59 processes of care that are included in the ADA's comprehensive medical evaluation, the current study examined a total of nine individual processes of care that represent a total of five categories. Inadequate care was considered to be present if standards set by the ADA guidelines were not met.[6] Categories of inadequate care were defined as: 1) laboratory evaluation, defined as meeting both A1c and cholesterol test standards. Standards for A1c testing was the presence of two or more A1c tests in the past year and cholesterol testing was the presence of at least one cholesterol test in the past year. 2) physical examination, defined as meeting both foot and eye exam standards. Standards for foot exam was at least one foot exam in the past year, and for eye exam, it was at least one eye exam in the prior two years. 3) pharmacologic therapy defined as meeting medication standards including antihyperglycemic medication adherence, high-intensity statin therapy among patients with established atherosclerotic cardiovascular disease (ASCVD), and hypertension treatment with established hypertension. 4) lifestyle management, defined as presence of a modified diet; and, 5) immunization, defined as having received an influenza vaccination in the prior year. A national estimate for the presence of each of the five categories of diabetes inadequate care was calculated as a proportion (presence of inadequate care versus no presence). An additional measure was used to estimate the total amount of inadequate care based on the total number of individual processes of care identified as inadequate between 0 (no inadequate care identified) up to 9 (every single process of care identified as inadequate). The measure of total inadequate care was divided into four categories: no inadequate care (0 processes identified as inadequate), some (1-2 processes identified), moderate (3-4 processes identified), and high (5 or more processes identified). With the exception of pharmacologic therapy, the individual processes of care were self-reported questions gathered by the diabetes care survey.[17] Pharmacologic therapy processes of care were derived from MEPS medical conditions and prescribed medicines data files.[21,22]

Medication adherence was measured using proportion of days covered (PDC) method. A measure of at least 80% was considered adherent. PDC was calculated by total number of days supply of filled antihyperglycemics of any type, divided by total days. Days began at first prescription fill of antihyperglycemics detected after index date. In the case of using multiple antihyperglycemics, a fill of any antihyperglycemic was considered adherent. Highintensity statins were defined to be Atorvastatin – 40-80 mg or Rosuvastatin – 20-40 mg.[6]

Hypertension treatment was defined to be a prescription of ACE inhibitors, Angiotensin receptor blockers (ARBs), Thiazide-like diuretics, Dihydropyridine calcium channel blockers.[6]

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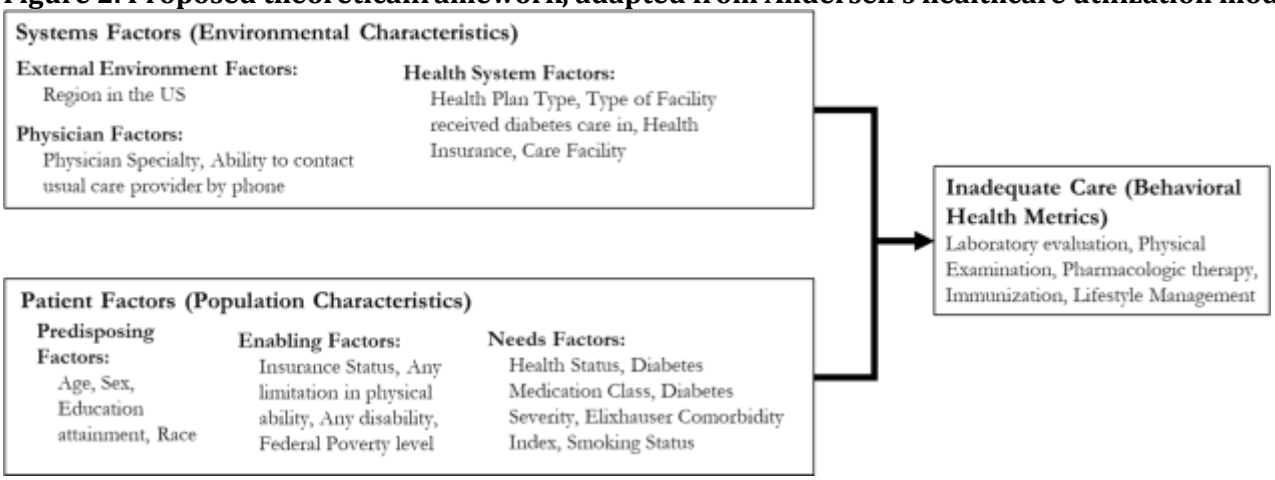
The secondary outcomes of interest are the associated characteristics of inadequate care. Andersen's behavior model of healthcare utilization was used to guide characteristic selection, in which the environment and population characteristics predict health behavior (Figure 2, below). Andersen's behavior model was adapted such that environment is considered to be healthcare system factors and physician factors. Population characteristics, including predisposing, enabling, and needs factors, were considered to be patient factors. And health behavior was considered to be one of five categories of inadequate care. Predisposing factors include age, sex (male or female), education attainment, and race. Enabling factors include insurance coverage, any limitation in physical function, presence of disability, and poverty level. Need factors include diabetes medication class, diabetes severity, Elixhauser Comorbidity Index, and smoking status.[23] Health system factors include health plan type, type of facility person receives diabetes care in, source of health insurance, and usual source of care. Physician characteristics include physician specialty, and if there was any difficulty contacting usual care provider by phone. The external environment includes geographic region. Table 1 lists the categories for each variable.

Any limitation in physical function isdefined by MEPS as presence of any: difficulty lifting 10 pounds, difficulty walking up 10 steps, difficulty walking 3 blocks, difficulty walking a mile, difficulty standing 20 minutes, difficulty bending or stooping, difficulty reaching over head, or difficulty using fingers to grasp.[16] Presence of disability is defined by MEPS as presence of any: blindness, deafness, serious cognitive difficulties, serious difficulty walking /climbing stairs, difficulty dressing/bathing, difficulty doing errands alone.[16] Poverty level is the federal poverty level, set by Department of Health and Human Services (HHS) each year.[24] Diabetes medication class is a metric that gauges the severity of diabetes based on the class of diabetes drug, based on ADA's diabetes pharmacologic step-therapy guidelines.[6] Patients taking only metformin and were not taking any additional antihyperglycemic drugs were classified as the first category, patients on antihyperglycemics other than metformin or insulin were classified as a second category, and patients that used insulin were classified as a third category. Diabetes severity was identified by using the Diabetes Complications Severity Index (DCSI) and is a 14-level metric that quantifies the severity of diabetes complications, including scores for neuropathy, cerebrovascular, cardiovascular, retinopathy, metabolic complications, nephropathy, and peripheral vascular disease.[25] Type of Facility received diabetes care in, is the facility(s) associated with prescribed antihyperglycemic medications, and usual source of care is the facility type in which the person considers their usual source of care.

Figure 2. Proposed theoreticalframework, adapted from Andersen's healthcare utilization model.[26]



2.4 Statistical Analysis

After the final cohort was identified, descriptive statistics were used to describe prevalence for each type of inadequate care, as well total inadequate care, which was divided into four categories and previously described. Bivariate analysis was used to describe the associated characteristics, utilizing t-tests for continuous variables and Chi-squared test for categorical variables. Survey weighted procedures were used for all analysis.

Some diabetes care survey responses included missing data points. Multiple imputation was used to impute missing data for variables eye exam, and foot exam, presence of a modified diet, A1c test, cholesterol test, and if received influenza vaccination. The multiple imputation method used was fully conditional specification, utilizing a logistic regression model including the imputed variables in addition to the associated characteristics of inadequate care previously mentioned.[27]

Using the imputation procedure, 18 missing values were filled for eye exam, 29 for foot exam, 13 for modified diet, 337 for A1c test, 19 for cholesterol test, and 22 for influenza vaccination.

Analyses were conducted with SAS® version 9.4 (SAS Institute Inc., Cary, NC), with significance set at $P < .05$. Survey weighted procedures were used for all analysis. This project was approved by the University of Houston Institutional Review Board under the exempt category.

3. Results

3.1 Study Population Characteristics

A total of 1,665 individuals were identified as meeting the inclusion criteria for the study, estimated to be represent 22,385,168 individuals after applying nationally representative survey weights. Prior to imputation procedures, 1.08% of observations had missing values for eye exam, 1.74% for foot exam, 0.78% for modified diet, 20.24% for A1c test, 1.14% for cholesterol tests, and 1.32% for influenza vaccination. Table 1, below, displays the baseline characteristics of the study cohort, identifying the mean and standard error for continuous variables and the frequency, weighted frequency, and proportional distribution for categorical variables.

Table 1. Characteristics of study cohort, using nationally representative survey weights. Weighted frequencies given as thousands of persons.

Variable (Continuous)	**Mean**	**Std Error**		**Variable (Categorical)**	**Frequency**	**Weighted Frequency**	**Percent**
Age	61.21	0.40		Usual diabetes care facility			
Years since diabetes diagnosis	13.08	0.35		None or unknown	1196	16,203	72.38
Diabetes Complications Severity Index	1.53	0.03		Medical office	413	5,498	24.56
Variable (Categorical)	**Frequency**	**Weighted Frequency**	**Percent**	Hospital outpatient	22	275	1.23
Sex				Emergency room	14	168	0.75
Female	875	10,913	48.75	Hospital inpatient	20	242	1.08
Male	790	11,472	51.25	Diabetes drug severity			
Education				Metformin only	540	7,208	32.20
0 - 8 years	189	1,878	8.39	Diabetes medications other than	545	7,465	33.35

				metformin and insulin			
Some High School	201	2,102	9.39	Insulin	580	7,712	34.45
Graduated High School	549	6,765	30.22	Physician specialty of diabetes care provider			
Some College	382	6,247	27.91	None or unknown	1275	17,285	77.22
Four or more years of college	344	5,394	24.10	Family practice	52	651	2.91
Race				Generalist	66	818	3.65
Hispanic	336	3,480	15.54	Internal Medicine	27	372	1.66
White	891	13,678	61.10	Other specialist	88	1,322	5.90
Black	308	3,181	14.21	Multiple specialists	157	1,938	8.66
Asian	72	1,232	5.51	Limitation in physical ability			
Other or Multiple	58	815	3.64	No	1038	14,326	64.00
Poverty Level				Yes	627	8,059	36.00
Poor	315	2,874	12.84	Presence of disability			
Near Poor	114	1,505	6.72	No	937	13,141	58.70
Low Income	266	3,531	15.77	Yes	728	9,244	41.30
Middle income	481	6,750	30.15	Gatekeeper plan			
High Income	489	7,725	34.51	No	1162	15,736	70.30
Smoking status				Yes	503	6,649	29.70
None	1456	19,614	87.62	Insurance type			
Not every day	66	843	3.76	No coverage	53	533	2.38
Every day	143	1,928	8.61	Medicare	313	4,100	18.35
Usual source of care				Other public	161	1,804	8.07
None	132	1,703	7.61	Private	415	6,944	31.07
Hospital clinic	412	5,137	22.95	Multiple	723	8,967	40.12
Non-hospital medical office	984	13,412	59.91	Any difficulty contacting usual			

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				care provider by phone			
Other facility type or unknown	137	2,134	9.53	No	1376	18,704	83.56
Region				Yes	289	3,681	16.44
Northeast	227	3,594	16.06	Elixhauser Comorbidity Index			
Midwest	328	4,633	20.70	1	288	4,290	19.16
South	772	9,819	43.86	2	738	9,713	43.39
West	338	4,339	19.38	3	374	4,858	21.70
				4+	265	3,524	15.74

3.2 Prevalence of Inadequate Care

The prevalence of inadequate care was estimated using nationally representative survey weights, with results displayed in table 2, below. It was estimated that 25.51% of the T2D population received inadequate lifestyle management and 32.39% received inadequate immunization. It was also estimated that 42.63% received inadequate pharmacologic therapy, 38.15% received inadequate physical examinations, and 38.15% received inadequate laboratory tests. Finally, it was estimated that 8.76% of individuals were had a high amount of inadequate care, 22.67% had moderate, 51.50% had some, and 17.07% of individuals had no inadequate care present.

Table 2. Prevalence of inadequate care among individuals with type 2 diabetes, using nationally representative survey weights. Weighted frequencies given as thousands of persons.

Inadequate Care	**Frequency n= 1665**	**Weighted Frequency n=22,385**	**Percent**
Inadequate Lifestyle Management			
Yes	420	5,711	25.51
No	1,245	16,674	74.49
Inadequate Immunization			
Yes	549	7,251	32.39
No	1,116	15,134	67.61
Inadequate Pharmacologic Therapy			
Yes	736	9,544	42.63
No	929	12,842	57.37
Inadequate Physical Examinations			

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Yes	628	8,541	38.15
No	1037	13,845	61.85
Inadequate Laboratory Tests			
Yes	469	6,332	28.29
No	1,196	16,053	71.71
Total Inadequate Care[a]			
None	288	3,822	17.07
Some	840	11,528	51.50
Moderate	387	5,075	22.67
High	150	1,961	8.76

[a]Total inadequate care was divided into 4 categories: None (0 processes identified as inadequate), some (1-2 processes identified), moderate (3-4 processes identified), and high (5 or more processes identified). Processes measured include: 1) A1c test standards, 2) cholesterol test standards, 3) foot exam standards, 4) eye exam standards, 5) antihyperglycemic medication adherence, 6) atherosclerotic cardiovascular disease (ASCVD) treatment among those with ASCVD, 7) hypertension treatment among those with hypertension, 8) a modified diet, and 9) received influenza vaccination.

3.3 Associated Characteristics of Inadequate Care

For each of the five categories of inadequate care, those who received inadequate care were compared to those that did not receive inadequate care (Table 3, below). Statistical significance between the two groups was calculated using t-tests for continuous variables and Chi-squared test for categorical. Age, years since diabetes diagnosis, and Diabetes Complications Severity Index were found to be significantly different between the two groups for all five categories of inadequate care. Among categorical variables, only race was found to be significantly associated with being on a modified diet. Six categorical variables were significantly associated with receiving an influenza vaccine – education, smoking status, usual source of care, usual diabetes care facility, if the individual was on a gatekeeper health plan, and insurance type. Nine categorical variables were significantly associated with receiving adequate pharmacologic therapy – sex, education, poverty level, region, diabetes drug severity,limitation in physical ability, Presence of disability, insurance type, and Elixhauser Comorbidity Index. Seven categorical variables were significantly associated with receiving adequate physical examinations – race, usual diabetes care facility, diabetes drug severity, physician specialty of diabetes care provider,presence of disability, if the individual was on a gatekeeper health plan, and insurance type. Eight categorical variables were significantly associated with receiving adequate laboratory tests – education, usual source of care, usual diabetes care facility, diabetes drug severity, physician specialty of diabetes care provider, presence of disability, insurance type, and Elixhauser Comorbidity Index.[23]

Table 3. Comparison of unadjusted characteristics of those who received inadequate care versus those who did not, for five categories of inadequate care, among individuals with type 2 diabetes, using nationally representative survey weights. Weighted frequencies given as thousands of persons.

	Inadequate Lifestyle Management		Inadequate Immunization		Inadequate Pharmacologic Therapy		Inadequate Physical Examinations		Inadequate Laboratory Tests	
	Yes (n=415;	No (n=1,250	Yes (n=548;	No (n=1,117;	Yes (n=736;	No (n=929;	Yes (n=627;	No (n=1,048;	Yes (n=475;	No (n=1,190;

	5,627)[a]	; 16,758)[a]	7,267)[a]	15,118)[a]	9,544)[a]	12,842)[a]	8,555)[a]	13,830)[a]	6,372)[a]	16,013)[a]
Variable (Continuous)	**Mean (Standard Error)**									
	p<. 0001*		p<. 0001*		p<.0 001*		p<. 0001*		p<. 0001*	
Age	61.30 (0.74)	61.18 (0.48)	56.58 (0.64)	63.43 (0.42)	63.21 (0.53)	59.72 (0.55)	59.13 (0.58)	62.49 (0.50)	59.13 (0.71)	62.04 (0.45)
	p<. 0001*		p<. 0001*		p<.0 001*		p<. 0001*		p<. 0001*	
Years since diabetes diagnosis	14.41 (0.62)	12.64 (0.38)	11.24 (0.52)	13.97 (0.42)	13.94 (0.64)	12.45 (0.34)	11.10 (0.57)	14.31 (0.45)	11.28 (0.44)	13.80 (0.45)
	p<. 0001*		p<. 0001*		p<.0 001*		p<. 0001*		p<. 0001*	
Diabetes Complications Severity Index	1.55 (0.04)	1.52 (0.03)	1.44 (0.05)	1.57 (0.04)	1.86 (0.04)	1.28 (0.03)	1.42 (0.04)	1.60 (0.04)	1.42 (0.04)	1.57 (0.03)
Variable (Categorical)	**Proportion, by weighted frequency**									
Sex	p=. 2751		p= .3569		p=.0 453*		p=. 3876		p=. 5442	
Female	46.09 %	49.65%	46.99 %	49.59%	52.13 %	46.24%	50.33 %	47.77%	47.40 %	49.29%
Male	53.91 %	50.35%	53.01 %	50.41%	47.87 %	53.76%	49.67 %	52.23%	52.60 %	50.71%
Education	p=. 2491		p=. 0007*		p=.0 296*		p=. 1078		p=. 0287*	
0 - 8 years	9.08%	8.15%	9.07%	8.06%	9.85%	7.30%	9.63%	7.62%	9.13%	8.09%
Some High School	9.10%	9.48%	10.96 %	8.63%	10.08 %	8.88%	11.80 %	7.90%	12.07 %	8.32%
Graduated High School	33.31 %	29.18%	34.91 %	27.97%	32.83 %	28.28%	30.00 %	30.36%	28.70 %	30.83%
Some College	29.14 %	27.49%	28.35 %	27.69%	26.58 %	28.89%	26.38 %	28.85%	23.57 %	29.63%
Four or more years of college	19.36 %	25.69%	16.71 %	27.65%	20.66 %	26.65%	22.19 %	25.28%	26.53 %	23.13%
Race	p=. 0242*		p= .1060		p=. 4265		p=. 0078*		p=. 0723	
Hispanic	10.70 %	17.17%	16.64 %	15.01%	16.59 %	14.76%	19.59 %	13.04%	15.70 %	15.48%

White	67.58 %	58.93%	56.25 %	63.43%	58.67 %	62.91%	55.72 %	64.43%	56.59 %	62.89%
Black	12.43 %	14.81%	16.07 %	13.31%	15.99 %	12.89%	14.16 %	14.24%	17.75 %	12.80%
Asian	5.95%	5.35%	6.04%	5.25%	5.58%	5.45%	6.27%	5.03%	7.14%	4.86%
Other or Multiple	3.34%	3.74%	5.00%	2.99%	3.18%	3.98%	4.27%	3.25%	2.83%	3.96%
Poverty Level	p=. 1888		p= .0667		p=.0 001*		p=. 7669		p=. 3236	
Poor	13.06 %	12.76%	16.25 %	11.20%	15.07 %	11.18%	13.03 %	12.72%	13.73 %	12.48%
Near Poor	7.49%	6.46%	6.84%	6.67%	8.06%	5.73%	6.12%	7.10%	7.65%	6.35%
Low Income	16.22 %	15.63%	16.69 %	15.34%	18.71 %	13.59%	17.32 %	14.82%	16.35 %	15.55%
Middle income	33.97 %	28.87%	30.44 %	30.02%	29.47 %	30.66%	29.72 %	30.42%	32.70 %	29.14%
High Income	29.26 %	36.28%	29.79 %	36.78%	28.68 %	38.84%	33.81 %	34.94%	29.58 %	36.48%
Smoking status	p=. 1584		p=. 0024*		p=. 8404		p=. 7014		p=. 6325	
None	85.44 %	88.35%	82.66 %	90.01%	87.18 %	87.95%	88.54 %	87.05%	86.56 %	88.04%
Not every day	5.63%	3.14%	5.22%	3.06%	3.69%	3.82%	3.59%	3.87%	4.52%	3.47%
Every day	8.93%	8.51%	12.11 %	6.93%	9.13%	8.23%	7.87%	9.07%	8.92%	8.49%
Usual Source of Care	p=. 9320		p=. 0297*		p=. 2752		p=. 1450		p=. 0280*	
None	7.44%	7.66%	10.68 %	6.13%	9.06%	6.52%	9.86%	6.21%	9.43%	6.88%
Hospital clinic	22.36 %	23.15%	23.46 %	22.70%	23.69 %	22.40%	23.20 %	22.79%	27.59 %	21.10%
Non-hospital medical office	61.45 %	59.40%	55.31 %	62.13%	57.11 %	62.00%	58.26 %	60.93%	53.76 %	62.36%
Other facility type or unknown	8.75%	9.80%	10.56 %	9.04%	10.14 %	9.09%	8.67%	10.07%	9.21%	9.66%
Region	p=. 2307		p= .7783		p=.0 005*		p=. 8343		p=. 3284	
Northeast	17.44 %	15.59%	13.52 %	17.27%	11.77 %	19.24%	14.95 %	16.74%	15.40 %	16.32%
Midwest	21.97 %	20.27%	21.31 %	20.40%	19.33 %	21.72%	20.06 %	21.09%	18.25 %	21.67%

South	45.55 %	43.30%	44.49 %	43.57%	50.02 %	39.29%	44.98 %	43.18%	43.70 %	43.93%
West	15.04 %	20.84%	20.68 %	18.76%	18.88 %	19.75%	20.01 %	18.99%	22.64 %	18.09%
Usual Diabetes Care Facility	p=. 9864		p=. 0323*		p=. 5433		p<. 0001*		p<. 0001*	
None or unknown	71.58 %	72.65%	75.26 %	71.00%	74.15 %	71.06%	80.77 %	67.19%	79.65 %	69.49%
Medical office	25.30 %	24.31%	22.63 %	25.49%	22.85 %	25.83%	16.41 %	29.60%	17.08 %	27.54%
Hospital outpatient	1.35%	1.19%	0.33%	1.66%	1.17%	1.27%	0.84%	1.47%	1.10%	1.28%
Emergency room	0.83%	0.72%	1.24%	0.51%	0.49%	0.95%	0.88%	0.67%	0.39%	0.89%
Hospital inpatient	0.94%	1.13%	0.54%	1.34%	1.33%	0.89%	1.08%	1.08%	1.77%	0.80%
Diabetes drug severity	p=. 3396		p= .1405		p=.0 014*		p<. 0001*		p=.0 0161*	
Metformin only	29.08 %	33.25%	33.15 %	31.75%	37.51 %	28.25%	41.05 %	26.73%	36.90 %	30.33%
Diabetes medications other than metformin and insulin	33.82 %	33.19%	36.29 %	31.93%	30.99 %	35.10%	33.02 %	33.55%	33.58 %	33.25%
Insulin	37.09 %	33.56%	30.55 %	36.32%	31.50 %	36.65%	25.93 %	39.72%	29.52 %	36.41%
Physician specialty of diabetes care provider	p=. 1708		p= .1273		p=. 8015		p<. 0001*		p=. 0010*	
None or unknown	78.14 %	76.91%	80.10 %	75.83%	78.72 %	76.10%	85.03 %	72.39%	85.12 %	74.07%
Family practice	3.35%	2.76%	1.75%	3.46%	2.86%	2.94%	2.27%	3.30%	1.52%	3.46%
Generalist	1.85%	4.26%	4.53%	3.23%	3.14%	4.04%	2.53%	4.35%	2.94%	3.94%
Internal Medicine	0.79%	1.95%	1.69%	1.65%	1.67%	1.65%	0.83%	2.17%	1.56%	1.70%

Other specialist	5.87%	5.91%	4.75%	6.46%	5.01%	6.57%	2.79%	7.83%	3.90%	6.70%
Multiple specialists	10.00 %	8.21%	7.17%	9.37%	8.61%	8.69%	6.55%	9.96%	4.96%	10.13%
Limitation in physical ability	p=. 1324		p= .1982		p<.0 001*		p=. 6861		p=. 6364	
No	60.35 %	65.22%	66.93 %	62.59%	55.54 %	70.28%	64.70 %	63.56%	65.06 %	63.57%
Yes	39.65 %	34.78%	33.07 %	37.41%	44.46 %	29.72%	35.30 %	36.44%	34.94 %	36.43%
Presence of disability	p=. 9692		p= .0641		p<.0 001*		p=. 0218*		p=. 0190*	
No	58.80 %	58.67%	62.65 %	56.81%	51.50 %	64.06%	62.88 %	56.12%	63.66 %	56.73%
Yes	41.20 %	41.33%	37.35 %	43.19%	48.50 %	35.94%	37.12 %	43.88%	36.34 %	43.27%
Gatekeeper plan	p=. 7664		p=. 0003*		p=. 0679		p=. 0066*		p=. 2510	
No	71.03 %	70.05%	61.76 %	74.40%	73.08 %	68.22%	65.04 %	73.55%	68.10 %	71.17%
Yes	28.97 %	29.95%	38.24 %	25.60%	26.92 %	31.78%	34.96 %	26.45%	31.90 %	28.83%
Insurance type	p=. 5328		p<. 0001*		p=.0 001*		p=. 0008*		p=. 0086*	
No coverage	1.33%	2.73%	3.89%	1.66%	3.00%	1.92%	3.42%	1.73%	3.86%	1.79%
Medicare	19.38 %	17.96%	12.54 %	21.09%	22.28 %	15.37%	17.20 %	19.01%	15.86 %	19.30%
Other public	8.68%	8.07%	12.17 %	6.33%	8.78%	7.80%	8.61%	7.98%	10.70 %	7.24%
Private	32.82 %	30.42%	39.10 %	27.14%	24.52 %	35.85%	36.33 %	27.73%	33.47 %	30.05%
Multiple	37.79 %	40.82%	32.31 %	43.78%	41.42 %	39.05%	34.43 %	43.54%	36.11 %	41.63%
Any difficulty contacting usual care provider by phone	p=. 6388		p= .5372		p=. 4553		p=. 3461		p=. 0617	
No	82.75 %	83.83%	82.55 %	84.04%	82.73 %	84.17%	84.68 %	82.86%	85.95 %	82.60%

Yes	17.25 %	16.17%	17.45 %	15.96%	17.27 %	15.83%	15.32 %	17.14%	14.05 %	17.40%
Elixhauser Comorbidity Index	p=. 6138		p= .1358		p<.0 001*		p=. 5353		p=. 0194*	
1	18.84 %	19.27%	22.15 %	17.73%	12.93 %	23.80%	17.52 %	22.16%	22.92 %	17.67%
2	40.63 %	44.32%	44.52 %	42.85%	41.29 %	44.95%	41.25 %	48.92%	46.60 %	42.11%
3	23.57 %	21.08%	20.31 %	22.37%	25.07 %	19.20%	17.67 %	26.85%	17.08 %	23.54%
4+	16.97 %	15.33%	13.02 %	17.05%	20.71 %	12.05%	23.56 %	2.07%	13.39 %	16.68%

*Denotes statistical significance (p<0.05). P value calculated using t-tests for continuous variables and Chi-squared test for categorical. [a]Sample size is given by format (n = unweighted; weighted).

4. Discussion

This study estimated that about 83% (18.5 million individuals) of the T2D population experienced one or more type of inadequate care that was examined by the current study. Additionally, it was estimated that about 31% or 7 million individuals had a moderate level of inadequate care or higher, indicating that among these individuals, there were at least three processes of care which were identified as deficient.

This study's cohort sample size represented approximately 22.4 million individuals. Notably, these results differ from a similar study examining adherence to ADA's guidelines using MEPS that was published by Delevry et al. in 2020.[7] Compared to the 22.4 million sample size of the current study, the Delevry study examined a sample size representing 26.3 million individuals. The likely reasons for discrepancy are that the current study used several additional exclusion and inclusion criteria that differed to the Delevry study– namely, the current study required a diagnosis of T2D, as well as a confirmed antihyperglycemic prescription. In the Delevry study, it was found that only 7.8% of the sample adhered to all ADA guidelines that were measured, compared to approximately 17.1% of the current study's sample in which no inadequate care was found, which is a substantial difference. A portion of this difference in results is that the Delevry study looked at the blood pressure measurement and dental examination as part of the ADA guidelines, in which the current study did not examine. There are additional differences in the prevalence estimated in the current study compared to the Delevry study in that the prior study found about a 40% adherence rate for the metrics of A1c test, foot exam, eye exam, and influenza vaccination. Conversely, the current study found that about 60% had received adequate foot and eye exams, 72% received adequate laboratory tests, comprising both cholesterol and A1c tests, and about 67% had received the influenza vaccine. A part of the discrepancy may be explained in a difference in handling missing values. The current study used imputation to deal with missing data, such as responses indicating A1c testing; however, the Delevry study did not mention how missing data was handled. In addition, the Delevry study used data from 2012 to 2017, so the adherence may have improved during that time. Another difference was that the current study used stricter inclusion and exclusion criteria when identifying the study population. Regarding receiving inadequate physical examinations (foot and eye exam), the current study results were similar to previous studies that have examined the prevalence of these diabetes care measures. A study by Hatef et al. examined diabetic eye exams and found in the Medicaid population, 46-64% of patients received an eye exam depending on year. [28] National prevalence of diabetic foot exams among the Centers for Medicare & Medicaid Services population was reported to be 76.17%.[29]

Other previous studies have individually examined the prevalence of several individual processes of T2D care to varying degrees. A study by Imai et al. found that adherence to A1c testing guidelines was 50%, while a study by Lian et al. found 58.5% of their tested population met adherence guidelines for A1c testing. [30,31] Both of these studies

found A1c testing adherence to be lower than the current study, which found that about 72% received adequate laboratory tests. However, both Imai and Lian studies used stricter criteria when it came to identifying compliance regarding A1c testing.

ADA guidelines, for instance require more frequent A1c tests among those with uncontrolled diabetes, while the current study used the most conservative scenario of a minimum of twice in a year.[6] For the metric of influenza vaccination for the T2D population, the current study is consistent with previous literature. The rate of influenza vaccination among the diabetes population was previously estimated to be about 62% in a paper published in 2016 by the National Center for Health Statistics and about 65% by a study by Garcia et al. which are both similar to the 68% rate estimated by the current study.[32,33]

Notably, the current study found that all categories of inadequate care measured were observed at a rate of 25% or higher among theT2D population. It is evident there is room for improvement regarding care meeting recommended ADA guidelines. The highest rate of inadequate care detected was in the category of inadequate pharmacologic therapy, in which inadequate care was estimated to be about 43%. Further, the antihyperglycemics medication adherence measured used by the current study was a conservative one, requiring only an 80% PDC for any antihyperglycemic. However, it should be noted that hypertension and ASCVD treatments were limited to the most commonly used antihypertensives in the diabetic population and high intensity anticholesterol agents only.

The second portion of the current study examined associated characteristics of inadequate care, identifying multiple characteristics for each category of inadequate care. Some characteristics of inadequate care metrics have been investigated by previous studies. In the previously referenced study be Delevry et al., socioeconomic status, smoking status, and race were predictive of adherence to ADA guidelines, which is consistent with the current study that found these variables to be associated with one or more categories of inadequate care.[7] Prior literature indicates that significant predictors of diabetic eye and foot exam include age, income level, education, insurance status, and race.[34–36] However, in the current study, race and poverty level were not significant associated characteristics. One difference between the studies was that the reference studies examined National Health and Nutrition Examination Survey (NHANES) data from around 2005 – 2015, and had different inclusion and exclusion criteria, as well as utilizing multivariate models.[34,36]

Of the 19 variables examined by this study, 18 were found to be significantly associated with at least one category of inadequate care that was studied, including external environment, patient, and systems factors. This was consistent with prior literature. A study by Okemah et al. investigated clinical inertia, defined as a failure to initiate or intensify treatment according to guidelines, and found that predictors of clinical inertia were a mix of interactions between patient, physician, and health-care system factors.[37] This paradigm remains true for this phenomenon of clinical inertia, or adherence to guidelines, among the diabetes population - studies examining strategies to improve diabetes care suggest systems and processes are a major driver in quality of diabetes care.[38– 42]However, previous studies, including the previously referenced Delevry, Imai, and Garcia studies, that estimate predictors of care or evaluate health outcomes resulting from inadequate care, lack the inclusion of health systems and process variables, such as physician specialty or type of facility patient received care in.[7,30,33,43–45]The current study found that these systems and processes variables were each associated with multiple types of inadequate care, namely, usual source of care was associated with receiving inadequate immunization and receiving inadequate laboratory tests, facility type in which diabetes care was received was associated with inadequate immunizations and receiving inadequate physical examinations and laboratory tests, physician specialty that provided diabetes medication prescription was associated with receiving inadequate physical examinations and laboratory tests, and having a gatekeeper type insurance plan was associated with inadequate immunizations and receiving inadequate physical examinations. However, it should be noted that the current study only looked at unadjusted associations, so additional analysis is called for to further examine these factors while adjusting for covariates.

The results regarding associated characteristics of inadequate care should be viewed as exploratory because the variables were not adjusted for covariates in the current study. A follow-up study is required to reinforce these results and provide additional context. Because many outcomes were tested, there is a possibility of type II statistical

error occurring. As additional MEPS data is published, this study could be repeated to confirm and reinforce the results. There are some additional limitations with the MEPS data that was used for this study. Some variables within MEPS are self-reported, such as smoking status, and other variables, such as race, are imputed when missing, which may cause certain biases to be present including reporting bias, recall bias, and response bias. Those that were not in-scope of the MEPS survey for the full year were also excluded, such as those that moved out of the country, died, or were otherwise unreachable. In addition, some processes of care variables, including A1c tests, cholesterol tests, foot, and eye examinations were imputed when missing, which may cause bias in results.

It should be noted that the generalizability of prevalence and associated characteristics of inadequate care is limited to the T2D population. However, the methodology used in the current study could be adapted to other chronic conditions, such as heart disease. It is also important to note that an important detail of the current study are the definitions of inadequate care, and the source used for their definitions. Any change in the definitions used for inadequate care would dramatically change study results. The current study relied on ADA standards of care for developing study definitions; however, diabetes care guidelines differ around the world. The inadequate care categories used for the current study were chosen as a subset from the ADA's Comprehensive Medical Evaluation.[6] The categories were chosen instead of examining individual processes in order to provide conceptual results that are understandable and avoid the information overload that would result from a piecemeal breakdown of individual processes.

The current study has several practical implications that should be highlighted. First, inadequate care is a prevalent issue that is alarming, especially the finding that about 43% of individuals were identified as having received inadequate pharmacologic therapy. These findings warrant additional research that examines health outcomes resulting from inadequate care, such as investigating their effect on healthcare resource utilization. The current study also suggested that systems and physician factors, in addition to patient factors are associated with inadequate care, despite previous studies on this topic failing to control for system and physician factors in their models. Models testing inadequate care could be improved by using theoretic framework that incorporates systems and physician factors. Future research seeking to expand on the issue of inadequate care should look to develop a model explaining inadequate care that incorporates patient and health systems factor and evaluate the effect of each type of inadequate care on health outcomes.

5. Conclusion

Inadequate care is a pervasive issue in the management of T2D. In each of the five categories of inadequate care examined, prevalence was over 25%, and 83% of individuals were identified as receiving inadequate care in one or more categories. A total of 18 out of 19 variables examined, including health system, physician, and patient factors, were significantly associated with at least one category of inadequate care. These findings suggest that additional research is warranted to further expand on the causes and consequences of inadequate care. It is important to acknowledge that the current study is exploratory in nature and additional research of this topic is needed to ascertain implications regarding the causes and outcomes of inadequate care.

Author Contribution

Conception and design: BL, SA, LL, EE, SS, SSS; Analysis of data: BL; drafting the article or revising it critically: BL, SA, LL, EE, SSS; final approval of the version to be submitted: BL, SA, LL, EE, SS, SSS.

Declaration of competing interest

All authors declare no conflicts of interest.

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