



Original Investigation | Nephrology

# Concordance With Screening and Treatment Guidelines for Chronic Kidney Disease in Type 2 Diabetes

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## Abstract

**IMPORTANCE** Chronic kidney disease (CKD) is an often-asymptomatic complication of type 2 diabetes (T2D) that requires annual screening to diagnose. Patient-level factors linked to inadequate screening and treatment can inform implementation strategies to facilitate guideline-recommended CKD care.

**OBJECTIVE** To identify risk factors for nonconcordance with guideline-recommended CKD screening and treatment in patients with T2D.

**DESIGN, SETTING, AND PARTICIPANTS** This retrospective cohort study was performed at 20 health care systems contributing data to the US National Patient-Centered Clinical Research Network. To evaluate concordance with CKD screening guidelines, adults with an outpatient clinician visit linked to T2D diagnosis between January 1, 2015, and December 31, 2020, and without known CKD were included. A separate analysis reviewed prescription of angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs) and sodium-glucose cotransporter 2 (SGLT2) inhibitors in adults with CKD (estimated glomerular filtration rate [eGFR] of 30-90 mL/min/1.73 m<sup>2</sup> and urinary albumin-to-creatinine ratio [UACR] of 200-5000 mg/g) and an outpatient clinician visit for T2D between October 1, 2019, and December 31, 2020. Data were analyzed from July 8, 2022, through June 22, 2023.

**EXPOSURES** Demographics, lifestyle factors, comorbidities, medications, and laboratory results.

**MAIN OUTCOMES AND MEASURES** Screening required measurement of creatinine levels and UACR within 15 months of the index visit. Treatment reflected prescription of ACEIs or ARBs and SGLT2 inhibitors within 12 months before or 6 months following the index visit.

**RESULTS** Concordance with CKD screening guidelines was assessed in 316 234 adults (median age, 59 [IQR, 50-67] years), of whom 51.5% were women; 21.7%, Black; 10.3%, Hispanic; and 67.6%, White. Only 24.9% received creatinine and UACR screening, 56.5% received 1 screening measurement, and 18.6% received neither. Hispanic ethnicity was associated with lack of screening (relative risk [RR], 1.16 [95% CI, 1.14-1.18]). In contrast, heart failure, peripheral arterial disease, and hypertension were associated with a lower risk of nonconcordance. In 4215 patients with CKD and albuminuria, 3288 (78.0%) received an ACEI or ARB; 194 (4.6%), an SGLT2 inhibitor; and 885 (21.0%), neither therapy. Peripheral arterial disease and lower eGFR were associated with lack of CKD treatment, while diuretic or statin prescription and hypertension were associated with treatment.

(continued)

## Key Points

**Question** What patient-level risk factors are associated with inadequate screening and treatment for chronic kidney disease (CKD) among people with type 2 diabetes (T2D)?

**Findings** In this cohort study of 316 234 participants with T2D, fewer than 25% received guideline-recommended CKD screening, and patient-level factors such as Hispanic ethnicity and comorbid cardiovascular disease were associated with concordance with screening recommendations. Treatment with sodium-glucose cotransporter 2 inhibitors occurred among fewer than 5%, and people with peripheral arterial disease or lower kidney function were less likely to receive treatment.

**Meaning** These findings may inform strategies to improve CKD screening and treatment in people with T2D.

## + Supplemental content

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Abstract (continued)

**CONCLUSIONS AND RELEVANCE** In this cohort study of patients with T2D, fewer than one-quarter received recommended CKD screening. In patients with CKD and albuminuria, 21.0% did not receive an SGLT2 inhibitor or an ACEI or an ARB, despite compelling indications. Patient-level factors may inform implementation strategies to improve CKD screening and treatment in people with T2D.

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## Introduction

Chronic kidney disease (CKD) affects more than 134 million people with type 2 diabetes (T2D) globally.<sup>1-3</sup> Due to the asymptomatic nature of early CKD, consensus guidelines recommend annual CKD screening with estimated glomerular filtration rate (eGFR) and urinary albumin-to-creatinine ratio (UACR) in this population.<sup>4,5</sup> However, adherence to these guidelines remains inadequate. The United States Renal Data System reported that only 40% to 46% of people with T2D and without CKD receive proteinuria screening.<sup>6</sup> Understanding the patient-level risk factors associated with not receiving recommended primary CKD screening can inform implementation strategies to improve screening for people with T2D.

Underdiagnosis of CKD leads to undertreatment. A growing number of therapies improve kidney and cardiovascular outcomes, including angiotensin-converting enzyme inhibitors (ACEIs) or angiotensin receptor blockers (ARBs),<sup>7-9</sup> mineralocorticoid receptor antagonists,<sup>10</sup> glucagonlike peptide-1 receptor agonists,<sup>11</sup> and sodium-glucose cotransporter 2 (SGLT2) inhibitors.<sup>12-14</sup> However, prescription rates range from 20% to 75% for ACEIs or ARBs and 0.3% to 12% for SGLT2 inhibitors,<sup>15-20</sup> although UACR data could provide more accurate clinician uptake of these therapies by identifying patients with clear indications. Therefore, a cohort contemporary with US Food and Drug Administration (FDA)-approved indications for CKD treatment is necessary to assess clinician uptake and identify risk factors for not receiving treatment.

We characterized concordance with CKD screening guidelines in a nationally representative cohort, with the goal of identifying patient-level risk factors associated with nonconcordance. We similarly evaluated risk factors for lack of prescriptions for treatments to improve kidney outcomes in people with established CKD, specifically ACEI or ARB and SGLT2 inhibitor therapy. To accomplish these aims, we leveraged electronic health record data from 20 large health systems across the US that have mapped their data to the National Patient-Centered Clinical Research Network (PCORnet) common data model.

## Methods

### Study Population

The Patient-Centered Outcomes Research Institute (PCORI) created PCORnet to establish a national network of health care organizations, patient groups, and research institutions to improve medical research through clinical data.<sup>21</sup> Participating organizations map clinical data to a common data model.<sup>22</sup> In this study, we included data collected between January 1, 2014, and December 31, 2021, from 20 health systems across the US. We then generated 2 study cohorts to evaluate concordance with screening and treatment guidelines, respectively. The Duke Investigational Review Board approved this study and granted a waiver of informed consent for the use of deidentified data. The datasets generated for the current study are not publicly available due to PCORnet site and sponsor data use agreements but are available from the corresponding author on reasonable request. This study followed the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

The screening cohort included patients with T2D without known CKD who are sufficiently integrated into the health system to capture diabetes-related care. Adult patients aged 18 to 90 years with an outpatient visit between January 1, 2015, and December 31, 2020, with a corresponding T2D diagnosis (full list of diagnostic codes provided in eTable 1 in [Supplement 1](#)) and at least 2 outpatient visits in the previous 12 months were eligible. We excluded patients with a diagnosis of type 1 diabetes, no antiglycemic prescription in the 12 months before or 3 months after the index date, and eGFR of less than 60 mL/min/1.73 m<sup>2</sup> in the 12 months prior to the index date. The index date was defined as the first outpatient visit with a corresponding T2D diagnosis that fulfills these criteria.

The treatment cohort included patients with T2D, CKD, and indications for ACEI or ARB and SGLT2 inhibitor therapy. We restricted the cohort to those with outpatient clinician visits linked to a T2D diagnosis between October 1, 2019, and December 31, 2020, to coincide with the FDA approval for canagliflozin use to improve CKD outcomes on September 30, 2019. We did not analyze mineralocorticoid receptor antagonists use due to their relatively recent FDA approval for this indication in July 2021. We similarly did not assess glucagonlike peptide-1 receptor agonists since kidney outcomes data had not yet been published to support the use for this indication. Patients were also required to have an antiglycemic medication prescription within the health care system in the 12 months before or 3 months after the index date, an eGFR of 30 to 90 mL/min/1.73 m<sup>2</sup> (based on both the median and most recent creatinine measurement in the 12 months prior to the index date) and UACR of 200 to 5000 mg/g for all records within the 12 months prior to the index visit, and at least 1 serum potassium measurement within the 12 months prior to the index date with the most recent value decreasing less than 5 mEq/L (to convert to mmol/L, multiply by 1.0).

## Outcomes

The primary outcome for the screening cohort was concordance with guideline-recommended screening for CKD. We divided concordance into 3 levels: fully concordant, partially concordant, and nonconcordant. Full concordance required measurement of both serum creatinine levels and UACR within 15 months of the index visit date (ie, the 12-month guideline recommendation plus a 3-month grace period). Measurement of either creatinine level or UACR was considered partial concordance. As an exploratory outcome, we evaluated the association between concordance with screening guidelines and the composite outcome of all-cause mortality or all-cause hospitalization starting 15 months after the index visit date (ie, completion of the screening exposure window) until 5 years or study end. Mortality data were ascertained from site records and supplemented with external government and commercial sources using the Datavant platform (Datavant).

The primary outcome for the treatment cohort was prescription of ACEIs or ARBs and SGLT2 inhibitors. Full treatment required a prescription of both therapies in the 12 months before through 6 months after the index visit. Prescription for only 1 therapy was deemed partial treatment, and lack of prescription for either medication was considered no treatment.

## Risk Factors

We evaluated the association between key patient-level covariates deemed potentially relevant to receiving guideline-concordant clinical care. For the screening cohort, these exposures included demographic characteristics, lifestyle factors and comorbidities, prescribed medications, and laboratory results. To identify potential disparities in screening and treatment, race and ethnicity were ascertained via electronic health records and included the categories Black, Hispanic, White and other race or ethnicity (where the latter category included American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, multiracial, and other [these categories were consolidated owing to lower representation in the overall cohort]). We applied the updated 2021 definition for eGFR that excluded the race modifier.<sup>23</sup> Covariates for the treatment cohort also included serum potassium level. A full list of covariates in each model is provided in eTable 2 in [Supplement 1](#).

## Statistical Analysis

Data were analyzed from July 8, 2022, through June 22, 2023. Categorical values within cohort summaries are listed as counts with percentages; continuous variables, as mean and SD for normally distributed variables; and median with IQR for variables with a skewed distribution. For death and hospitalization, incidence rates were computed per 100 person-years.

To determine factors associated with nonconcordance with CKD screening guidelines, we dichotomized the outcome into nonconcordant vs fully or partially concordant (reference) groups due to the relatively small number of patients in the fully concordant group. However, we preserved the 3-group separation for a sensitivity analysis. We used robust Poisson regression to model binary outcomes yielding relative risks.<sup>24</sup> The treatment cohort was also dichotomized into prescription of full or partial treatment (reference) vs no treatment and analyzed using robust Poisson regression. Exploratory and sensitivity analyses are provided in eTable 3 in [Supplement 1](#).

We imputed missing categorical variables with the respective population mode: race (White), ethnicity (non-Hispanic), and smoking status (nonsmoker). Missingness was 3.5% for race and ethnicity and less than 6.0% for smoking. Missing body mass index values (<5.0%) were imputed with the sex-specific mean, and missing systolic and diastolic blood pressures (7.0%) were imputed with the respective population means. Due to higher levels of missingness for hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) levels (30.8%) and eGFR (26.5%) (to convert to proportion of total hemoglobin, multiply by 0.01), we modeled these variables as categorical variables, with 1 level of the variable designated for missing. Analyses were performed by the Duke Clinical Research Institute, Durham, North Carolina, using SAS, version 9.4 (SAS Institute Inc). Two-sided  $P < .05$  indicated statistical significance.

## Results

### Concordance With CKD Screening Guidelines

The screening cohort consisted of 316 234 patients with T2D and without known CKD. The median age was 59 (IQR, 50-67) years; 51.5% of the patients were women and 48.5% were men. In terms of race and ethnicity, 21.7% of patients were Black, 10.3% were Hispanic, 67.6% were White, and 7.5% were of other race or ethnicity (including American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, multiracial, and other) (**Figure** and **Table 1**). The median eGFR was 88.1 (IQR, 76.0-99.2) mL/min/1.73 m<sup>2</sup>. A total of 24.9% of patients received creatinine and UACR screening during the 15 months following the index visit (ie, fully concordant) (eTable 4 in [Supplement 1](#)). Of the 56.5% of patients who received either creatinine or UACR screening (ie, partially concordant [ $n = 178\,524$ ]), most received the creatinine assessment (175 152 [98.1%] or 55.4% of the total population). A total of 58 905 patients (18.6%) received no screening during the follow-up period (ie, nonconcordant). Screening rates were similar for the 132 108 patients (41.8%) receiving ACEI or ARB therapy (108 317 [82.0%] received at least partial screening) compared with those not receiving ACEI or ARB (149 012 of 184 126 [80.9%]) (eTable 5 in [Supplement 1](#)).

**Table 2** lists the associations between clinical factors and the relative risk (RR) of nonconcordance with CKD screening guidelines. Older patients (RR of nonconcordance per 5-year increase in age, 0.97 [95% CI 0.97-0.98]) and women (RR, 0.97 [95% CI, 0.96-0.99]) experienced a lower risk of nonconcordance with screening guidelines. Race was associated with the risk of nonconcordance with screening guidelines. The risk of nonconcordance with screening guidelines was also significant for people of Hispanic ethnicity (RR, 1.16 [95% CI, 1.14-1.18]). Compared with private insurance, Medicare or Medicaid (RR, 1.03 [95% CI, 1.01-1.05]) and other insurance coverage (RR, 1.12 [95% CI, 1.10-1.15]) were associated with a higher RR of not receiving CKD screening. Overall, cardiovascular comorbidities, including heart failure, peripheral arterial disease, and hypertension, were associated with a lower risk of nonconcordance with screening guidelines during the follow-up period. Stroke or transient ischemic attack were notable exceptions. A greater risk for nonconcordance was noted for people prescribed ACEIs or ARBs or statins, and a lower risk was noted for those prescribed mineralocorticoid receptor antagonists. Compared with those with HbA<sub>1c</sub>



**Table 1. Baseline Characteristics Stratified by Concordance With CKD Screening Guidelines in Patients With Type 2 Diabetes and Without Known CKD**

Characteristic	Patient group <sup>a</sup>		
	Fully or partially concordant (n = 257 329) <sup>b</sup>	Nonconcordant (n = 58 905)	All (N = 316 234)
<b>Demographic</b>			
Age at visit, median (IQR), y	59.0 (50.0-67.0)	59.0 (50.0-68.0)	59.0 (50.0-67.0)
<b>Sex</b>			
Female	132 379 (51.4)	30 422 (51.6)	162 801 (51.5)
Male	124 590 (48.4)	28 483 (48.4)	153 433 (48.5)
<b>Race</b>			
Black	56 309 (21.9)	12 217 (20.7)	68 526 (21.7)
White	174 712 (67.9)	39 100 (66.4)	213 812 (67.6)
Other <sup>c</sup>	18 707 (7.3)	4869 (8.3)	23 576 (7.5)
Missing	7601 (3.0)	2719 (4.6)	10 320 (3.3)
<b>Hispanic ethnicity</b>			
No	228 524 (88.8)	48 171 (81.8)	276 695 (87.5)
Yes	23 912 (9.3)	8682 (14.7)	32 594 (10.3)
Missing	4893 (1.9)	2052 (3.5)	6945 (2.2)
<b>Insurance</b>			
Medicare or Medicaid	97 514 (37.9)	25 288 (42.9)	122 802 (38.8)
Other	21 508 (8.4)	6508 (11.0)	28 016 (8.9)
Private	83 460 (32.4)	19 183 (32.6)	102 643 (32.5)
Missing	54 847 (21.3)	7926 (13.5)	62 773 (19.9)
<b>Comorbidities and clinical data<sup>d</sup></b>			
BMI, median (IQR)	33.3 (28.9-39.0)	33.0 (28.5-38.4)	33.3 (28.9-38.9)
Overweight	55 277 (22.3)	12 617 (23.8)	67 894 (22.5)
Obesity	171 885 (69.3)	35 611 (67.0)	207 496 (68.9)
Current smoker	30 580 (11.9)	5756 (9.8)	36 336 (11.5)
Coronary artery disease	30 132 (11.7)	4466 (7.6)	34 598 (10.9)
Ischemic or hemorrhagic stroke	4554 (1.8)	806 (1.4)	5360 (1.7)
Transient ischemic attack	1843 (0.7)	293 (0.5)	2136 (0.7)
Heart failure	10 414 (4.0)	1386 (2.4)	11 800 (3.7)
Hospital heart failure	3288 (1.3)	363 (0.6)	3651 (1.2)
Peripheral arterial disease	13 067 (5.1)	1719 (2.9)	14 786 (4.7)
Lower extremity amputation	217 (0.1)	39 (0.1)	256 (0.1)
Hypertension	131 832 (51.2)	19 616 (33.3)	151 448 (47.9)
SBP, mean (SD), mm Hg	131.2 (17.6)	131.6 (17.5)	131.2 (17.6)
DBP, mean (SD), mm Hg	76.7 (10.8)	76.0 (11.0)	76.6 (10.8)
<b>Medications</b>			
ACEI or ARB	108 317 (42.1)	23 791 (40.4)	132 108 (41.8)
Thiazide diuretics	52 900 (20.6)	10 464 (17.8)	63 364 (20.0)
Loop diuretics	21 900 (8.5)	4411 (7.5)	26 311 (8.3)
sMRAs	6878 (2.7)	1205 (2.0)	8083 (2.6)
Statins	105 317 (40.9)	22 962 (39.0)	128 279 (40.6)
Insulin	58 300 (22.7)	15 084 (25.6)	73 384 (23.2)
<b>Laboratory data</b>			
HbA <sub>1c</sub> level, mean (SD), %	7.7 (2.0)	7.8 (2.8)	7.7 (2.1)
Missing	57 393 (22.3)	39 906 (67.7)	97 299 (30.8)
eGFR, mL/min/1.73 m <sup>2</sup> , median (IQR)	87.8 (75.8-98.8)	90.1 (77.6-101.7)	88.1 (76.0-99.2)
Missing	49 617 (19.3%)	34 122 (57.9)	83 739 (26.5)
UACR, median (IQR), mg/g	12.7 (6.1-33.0)	12.0 (6.0-28.0)	12.6 (6.0-33.0)
Missing	212 929 (82.7)	56 382 (95.7)	269 311 (85.2)

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CKD, chronic kidney disease; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>; SBP, systolic blood pressure; sMRAs, steroidal mineralocorticoid receptor agonist; UACR, urine albumin-to-creatinine ratio.

SI conversion factor: To convert HbA<sub>1c</sub> to proportion of total hemoglobin, multiply by 0.01.

<sup>a</sup> Data are expressed as No. (%) of patients unless otherwise noted. Concordance was defined as screening for both creatinine and UACR (fully concordant), creatinine or UACR (partially concordant), or neither (nonconcordant).

<sup>b</sup> The partially concordant cohort includes 175 152 patients who received only the eGFR laboratory measurement and 3372 patients who received only UACR measurement.

<sup>c</sup> Includes American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, multiracial, and other.

<sup>d</sup> Missingness for BMI (used to determine overweight and obesity) was 9313 (3.6%) for the partially or fully concordant group, 5789 (9.8%) for the nonconcordant group, and 15 102 (4.8%) for all patients.

(eTable 6 in Supplement 1). When we analyzed concordance as a 3-level outcome (fully concordant, partially concordant, or nonconcordant), most of the same risk factors persisted (eTable 7 in Supplement 1). Additionally, Black race was associated with higher odds of nonconcordance (odds ratio [OR], 1.16 [95% CI, 1.12-1.20] relative to the fully concordant group). Screening rates did not substantially differ by index date, including those in whom it occurred during the COVID-19 era (eFigure 1 in Supplement 1). Nonconcordance with screening guidelines during the 15-month follow-up period was associated with a lower risk of both all-cause mortality (adjusted hazard ratio, 0.66 [95% CI, 0.64-0.69]) and hospitalization (adjusted hazard ratio, 0.47 [95% CI, 0.46-0.48]) in both unadjusted and adjusted models and across sensitivity analyses (eTables 8 and 9 in Supplement 1).

**Table 2. Association Between Clinical Factors and Nonconcordance With CKD Screening Guidelines in Patients With Type 2 Diabetes and Without Known CKD**

Characteristic	RR (95% CI)	P value
Age per 5-y increase	0.97 (0.97-0.98)	<.001
Female sex	0.97 (0.96-0.99)	<.001
Race		
Black	1.00 (0.98-1.02)	.02
White	1 [Reference]	
Other <sup>a</sup>	1.03 (1.01-1.06)	
Hispanic ethnicity	1.16 (1.14-1.18)	<.001
Insurance		
Medicare or Medicaid	1.03 (1.01-1.05)	<.001
Other	1.12 (1.10-1.15)	
Missing	0.96 (0.93-0.98)	
Private	1 [Reference]	
Lower extremity amputation	1.06 (0.82-1.36)	.66
BMI per 5-kg/m <sup>2</sup> increase	0.99 (0.99-1.00)	.02
Current smoker <sup>b</sup>	0.94 (0.92-0.96)	<.001
Coronary artery disease	0.92 (0.90-0.95)	<.001
Stroke	1.11 (1.05-1.18)	<.001
Transient ischemic attack	1.12 (1.01-1.24)	.03
Heart failure	0.87 (0.83-0.92)	<.001
Peripheral arterial disease	0.83 (0.80-0.87)	<.001
Hypertension	0.86 (0.85-0.88)	<.001
SBP per 5-mm Hg increase	1.00 (1.00-1.00)	.56
DBP per 5-mm Hg increase	0.99 (0.99-1.00)	.03
ACEI or ARB	1.10 (1.09-1.12)	<.001
Thiazide diuretics	1.01 (0.99-1.03)	.36
Loop diuretics	1.02 (1.00-1.05)	.06
sMRAs	0.90 (0.85-0.94)	<.001
Statins	1.10 (1.08-1.11)	<.001
HbA <sub>1c</sub> level, %		
<6.5	0.97 (0.94-1.01)	<.001
6.5-7.9	1 [Reference]	
8.0-9.9	0.94 (0.91-0.98)	
≥10.0	1.04 (1.00-1.09)	
Missing	3.03 (2.96-3.10)	
eGFR, mL/min/1.73 m <sup>2</sup>		
60.0-89.9	0.73 (0.69-0.77)	<.001
90.0-119.9	0.81 (0.76-0.85)	
Missing	1.63 (1.54-1.72)	
≥120.0	1 [Reference]	
UACR measured	0.53 (0.51-0.55)	

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CKD, chronic kidney disease; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>; RR, relative risk; SBP, systolic blood pressure; sMRAs, steroidal mineralocorticoid receptor agonist; UACR, urine albumin-to-creatinine ratio.

SI conversion factor: To convert HbA<sub>1c</sub> to proportion of total hemoglobin, multiply by 0.01.

<sup>a</sup> Includes American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, multiracial, and other.

<sup>b</sup> Former or never smoker group served as reference group.

Treatment for CKD With Albuminuria

Of 4215 patients with CKD and albuminuria levels between 200 and 5000 mg/g, the median age was 69.0 (IQR, 61.0-76.0) years, 1800 (42.7%) were women, and 2415 (57.3%) were men (Table 3). The

Table 3. Baseline Characteristics Stratified by CKD Treatment in Patients With Type 2 Diabetes and CKD With Albuminuria

Characteristic	Patient group <sup>a</sup>		Overall (N = 4215)
	Prescribed ACEI or ARB and/or SGLT2 inhibitor (n = 3330) <sup>b</sup>	No treatment prescribed (n = 885)	
<b>Demographic</b>			
Age at visit, median (IQR), y	69.0 (60.0-75.0)	69.0 (62.0-76.0)	69.0 (61.0-76.0)
<b>Sex</b>			
Female	1431 (43.0)	369 (41.7)	1800 (42.7)
Male	1899 (57.0)	516 (58.3)	2415 (57.3)
<b>Race</b>			
Black	833 (25.0)	211 (23.8)	1044 (24.8)
White	2187 (65.7)	616 (69.6)	2803 (66.5)
Other <sup>c</sup>	214 (6.4)	45 (5.1)	259 (6.1)
Hispanic ethnicity	263 (7.9)	57 (6.4)	320 (7.6)
<b>Insurance</b>			
Medicare or Medicaid	1432 (43.0)	441 (49.8)	1873 (44.4)
Other	436 (13.1)	108 (12.2)	544 (12.9)
Private	559 (16.8)	185 (20.9)	744 (17.7)
Missing	903 (27.1)	151 (17.1)	1054 (25.0)
<b>Comorbidities and clinical data<sup>d</sup></b>			
BMI, median (IQR)	32.9 (28.6-38.0)	32.0 (27.9-37.9)	32.7 (28.4-38.0)
Overweight	742 (22.5)	211 (24.0)	953 (22.9)
Obesity	2246 (68.2)	552 (62.9)	2798 (67.1)
Current smoker	357 (10.7)	79 (8.9)	436 (10.3)
Coronary artery disease	1020 (30.6)	287 (32.4)	1307 (31.0)
Ischemic or hemorrhagic stroke	179 (5.4)	38 (4.3)	217 (5.1)
Transient ischemic attack	74 (2.2)	19 (2.1)	93 (2.2)
Heart failure	699 (21.0)	172 (19.4)	871 (20.7)
Hospital heart failure	283 (8.5)	73 (8.2)	356 (8.4)
Peripheral arterial disease	549 (16.5)	182 (20.6)	731 (17.3)
Lower extremity amputation	11 (0.3)	3 (0.3)	14 (0.3)
Hypertension	3056 (91.8)	764 (86.3)	3820 (90.6)
SBP, mean (SD), mm Hg	138.6 (19.5)	134.6 (17.7)	137.8 (19.2)
DBP, mean (SD), mm Hg	75.2 (11.7)	74.4 (12.0)	75.1 (11.8)
<b>Medications</b>			
ACEI or ARB	2898 (87.0)	0	2898 (68.8)
Thiazide diuretics	1106 (33.2)	125 (14.1)	1231 (29.2)
Loop diuretics	920 (27.6)	207 (23.4)	1127 (26.7)
sMRAs	241 (7.2)	49 (5.5)	290 (6.9)
Statins	2444 (73.4)	423 (47.8)	2867 (68.0)
SGLT2 inhibitor	121 (3.6)	0	121 (2.9)
Insulin	1902 (57.1)	477 (53.9)	2379 (56.4)
<b>Laboratory data</b>			
HbA <sub>1c</sub> level, mean (SD), %	7.8 (1.8)	7.8 (1.7)	7.8 (1.8)
Missing	234 (7.0)	60 (6.8)	294 (7.0)
eGFR, median (IQR), mL/min/1.73 m <sup>2</sup>	57.8 (45.8-72.1)	53.7 (41.2-69.1)	57.0 (45.0-71.6)
UACR, median (IQR), mg/g <sup>c</sup>	493.0 (300.0-990.6)	441.0 (293.0-884.0)	483.0 (299.2-963.0)
Serum potassium level, mean (SD), mEq/L	4.3 (0.4)	4.2 (0.4)	4.3 (0.4)

Abbreviations: ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CKD, chronic kidney disease; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>; SBP, systolic blood pressure; SGLT2, sodium-glucose cotransporter 2; sMRAs, steroidal mineralocorticoid receptor agonist; UACR, urine albumin-to-creatinine ratio.

SI conversion factors: To convert HbA<sub>1c</sub> to proportion of total hemoglobin, multiply by 0.01; potassium to mmol/L, multiply by 1.0.

<sup>a</sup> Data are expressed as No. (%) of patients unless otherwise noted.

<sup>b</sup> The partially treated cohort includes 42 patients who received only SGLT2 inhibitor and 3136 patients who received only ACEI or ARB.

<sup>c</sup> Includes American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, multiracial, and other.

<sup>d</sup> Missingness for BMI (used to determine overweight/obesity) was 38 (1.1%) for the group prescribed ACEIs or ARBs and/or SGLT2 inhibitors, 7 (0.8%) for the group with no treatment prescribed, and 45 (1.1%) for all patients.

racial and ethnic distributions resembled those of the screening cohort. The median eGFR was 57.0 mL/min/1.73 m<sup>2</sup> (IQR, 45.0-71.6 mL/min/1.73 m<sup>2</sup>), and the median UACR was 483 mg/g (IQR, 299.2-963.0 mg/g).

Of these patients with CKD, 3288 (78.0%) received an ACEI or an ARB; 194 (4.6%), an SGLT2 inhibitor; and 885 (21.0%), neither therapy. Only 152 patients (3.6%) were prescribed both an ACEI or an ARB and an SGLT2 inhibitor within 12 months before to 6 months after the index date. Peripheral arterial disease was associated with a higher risk of nontreatment (RR, 1.23 [95% CI, 1.06-1.43]) (Table 4). Each 1-meq/L increase in serum potassium level was associated with a lower risk of nontreatment (RR, 0.73 [95% CI, 0.63-0.83]). Additionally, hypertension, systolic blood pressure, and prescription of thiazide diuretics, loop diuretics, and statins were associated with a lower risk of nontreatment. As the eGFR increased, the risk of nontreatment decreased. Compared with patients with an eGFR of 60 to 90 mL/min/1.73 m<sup>2</sup>, patients with an eGFR of 30 to 44 mL/min/1.73 m<sup>2</sup> were

**Table 4. Association Between Clinical Factors and Nonprescription of CKD Treatment in Patients With Type 2 Diabetes and CKD With Albuminuria**

Characteristic	RR (95% CI)	P value
Age per 5-y increase	1.01 (0.98-1.04)	.49
Female sex	0.94 (0.83-1.06)	.29
Race		
Black	0.93 (0.8-1.08)	.23
White	1 [Reference]	
Other <sup>a</sup>	0.82 (0.62-1.08)	
Hispanic ethnicity	0.82 (0.65-1.03)	.09
Insurance		
Medicare or Medicaid	0.87 (0.75-1.02)	<.001
Other	0.81 (0.67-0.99)	
Missing	0.67 (0.55-0.81)	
Private	1 [Reference]	
Lower extremity amputation	1.21 (0.51-2.9)	.67
BMI		
<40 (5-Unit increase)	0.94 (0.88-0.99)	.12
≥40 (5-Unit increase)	1.15 (1.04-1.27)	
Current smoker <sup>b</sup>	0.90 (0.73-1.10)	.30
Coronary artery disease	1.11 (0.97-1.27)	.14
Ischemic or hemorrhagic stroke	0.94 (0.7-1.26)	.69
Transient ischemic attack	1.11 (0.76-1.65)	.58
Heart failure	0.94 (0.8-1.11)	.45
Peripheral arterial disease	1.23 (1.06-1.43)	.01
Hypertension	0.76 (0.65-0.89)	<.001
SBP per 5-mm Hg increase	0.95 (0.93-0.97)	<.001
DBP per 5-mm Hg increase	1.03 (0.99-1.06)	.12
Thiazide diuretics	0.46 (0.38-0.54)	<.001
Loop diuretics	0.82 (0.7-0.95)	.01
sMRAs	1.0 (0.77-1.3)	.98
Statins	0.49 (0.44-0.55)	<.001
HbA <sub>1c</sub> level	1.01 (0.98-1.04)	.55
UACR per 100-mg/g increase	0.99 (0.98-1.0)	.003
Serum potassium level	0.73 (0.63-0.83)	<.001
eGFR per 5-mL/min/1.73 m <sup>2</sup> increase	0.94 (0.92-0.96)	<.001
eGFR (categorical)		
30-44 mL/min/1.73 m <sup>2</sup>	1.66 (1.45-1.91)	<.001
45-59 mL/min/1.73 m <sup>2</sup>	1.19 (1.03-1.37)	
60-90 mL/min/1.73 m <sup>2</sup>	1 [Reference]	

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CKD, chronic kidney disease; DBP, diastolic blood pressure; eGFR, estimated glomerular filtration rate; HbA<sub>1c</sub>, hemoglobin A<sub>1c</sub>; RR, relative risk; SBP, systolic blood pressure; sMRAs, steroidal mineralocorticoid receptor agonist; UACR, urine albumin-to-creatinine ratio.

<sup>a</sup> Includes American Indian or Alaska Native, Asian, Native Hawaiian or Other Pacific Islander, multiracial, and other.

<sup>b</sup> Former or never smoker group served as reference group.

less likely to receive treatment (RR for nontreatment, 1.66 [95% CI 1.45-1.91]). Compared with private insurance, other insurance status (RR, 0.81 [95% CI, 0.67-0.99]) and missing insurance coverage information (RR, 0.67 [95% CI, 0.55-0.81]) were associated with lower relative risk of not receiving CKD treatment.

### Sensitivity Analysis

Measurement of UACR increased from 82 177 of 316 234 participants (26.0%) to 73 231 of 218 934 (33.4%) after restricting the cohort to patients with a HbA<sub>1c</sub> measurement in the past 12 months. In sensitivity analyses, those with UACR outside of the inclusion criteria for our study cohort (ie, UACR <200 mg/g, >5000 mg/g or missing) had higher rates of nontreatment than the study cohort, primarily driven by fewer ACEI or ARB prescriptions (eTable 10 in Supplement 1). When we raised the UACR cutoff to 300 mg/g, prescriptions for SGLT2 inhibitors slightly decreased from 4.6% to 4.4%. Prescriptions for both SGLT2 inhibitors and ACEIs or ARBs sharply declined in April 2020 commensurate with the onset of the COVID-19 pandemic (eFigure 2 in Supplement 1). However, prescriptions per month quickly returned to near-prepandemic levels. Concordance with treatment guidelines remained largely consistent across the study period, though a brief decline was apparent for index visits in November 2020 (eFigure 1 in Supplement 1).

### Discussion

In this cohort study of more than 300 000 people with T2D across the US, 24.9% received the recommended annual CKD screening. The clinical factors most strongly associated with nonconcordance with screening guidelines were Hispanic ethnicity, prior stroke or transient ischemic attack, ACEI or ARB prescription, and absence of HbA<sub>1c</sub> measurement. In contrast, patients with lower eGFR and select cardiovascular comorbidities were more likely to receive CKD screening. Additionally, despite the novel approach of evaluating only encounters after FDA approval of SGLT2 inhibitors to treat CKD and including patients who approximated the stringent inclusion criteria for the corresponding phase 3 studies, only 3.6% of patients with CKD received both ACEI or ARB and SGLT2 inhibitor therapies, primarily driven by a paucity of SGLT2 inhibitor prescriptions. Peripheral arterial disease and lower eGFR were associated with nontreatment.

Since CKD is often asymptomatic, screening is critical for diagnosis.<sup>25</sup> Despite consensus recommendations for annual CKD screening with serum creatinine and UACR measurement, only 26.0% of patients received UACR testing within 15 months in this study. This aligns with previously reported screening rates of 18% to 53%.<sup>6,15,17,26-28</sup> Screening with UACR measurement increased only to 33.4% when restricted to individuals with a recent HbA<sub>1c</sub> measurement (further supporting active diabetes management within that health system). These data suggest a substantial deficiency in CKD screening in routine clinical care. Most of our study cohort received screening for only serum creatinine (55.5%). However, UACR improves the sensitivity of CKD diagnosis in T2D since glomerular hyperfiltration may preserve eGFR despite the onset of kidney injury.<sup>29</sup>

Race and ethnicity were significantly associated with nonconcordance with CKD screening guidelines in our study. Hispanic ethnicity conferred the highest risk. Other race was also associated with nonconcordance with CKD screening guidelines. When concordance was considered as a 3-level outcome, Black race was also associated with higher odds of nonconcordance with screening guidelines. These disparities in CKD screening are especially notable in the context of the known disparities in CKD outcomes by race and ethnicity. For example, the risk of CKD progression is more than 3-fold higher among Black individuals compared with White individuals.<sup>30</sup> Furthermore, Black individuals comprise 37% of those receiving dialysis, despite representing 12% of the US population.<sup>6</sup>

To our knowledge, this study is the first to identify a difference in primary CKD screening by race and ethnicity. This finding contrasts with screening data from the American Medical Group Association, which revealed higher screening rates in people of Hispanic ethnicity.<sup>27</sup> Notably, our study population included nearly double the proportion of people of Hispanic ethnicity or Black race.

Recent data also suggest that individuals of Hispanic ethnicity and races other than White received superior UACR monitoring after diagnosis of CKD than people of White race.<sup>17</sup> However, our study focused on primary CKD screening and thus represents a fundamentally different study cohort and clinical question. Nevertheless, these discrepancies highlight the need for additional research to determine whether implementing primary CKD screening strategies in specific populations would effectively improve CKD outcomes and decrease disparities.

Unexpectedly, the patients who received full or partial CKD screening exhibited higher risks of hospitalization and death when compared with patients who received no CKD screening. Patients with better screening could have had more cumulative exposure to diabetes and other comorbidities that would increase the risk of adverse clinical events or the frequency of clinician visits (ie, screening opportunities). These differences in clinical outcomes highlight the systematic differences in the type of patients receiving guideline-recommended screening.

The emergence of effective treatments has further emphasized the significance of timely diagnosis of CKD. Only 3.6% of eligible patients were prescribed both an ACEI or ARB and an SGLT2 inhibitor, and 21.0% received neither therapy. Peripheral arterial disease conferred the highest risk of nontreatment. This association may reflect early clinician concerns and a temporary FDA black box warning regarding SGLT2 inhibitor use and lower extremity amputation. The relatively few amputations (0.3%) in this cohort limited more direct inferences related to this question. Of note, ACEI or ARB prescription was also less common in those with peripheral arterial disease for unclear reasons. Thus, failure to receive CKD therapies may mimic the paucity of other recommended therapies in people with peripheral arterial disease (eg, statins, antiplatelet therapies, and lifestyle counseling).<sup>31</sup> Serum potassium level was also linked to treatment, likely due to reverse causation (ie, ACEIs and ARBs raise potassium levels). Hypertension, diuretic use, and statin prescription were associated with lower risk of nontreatment, perhaps reflecting overlapping indications for therapy.<sup>32,33</sup>

These disparities can inform implementation strategies to improve CKD screening and treatment. The Indian Health Initiative<sup>34</sup> successfully implemented a systematic, population-based approach to increase screening and treatment, improve outcomes, and narrow disparities in CKD care. However, clinical trials have seldom demonstrated such a clinical benefit. For example, in the Improving Chronic Disease Management With Pieces (ICD-Pieces) randomized trial of 11 000 patients with CKD, T2D, and hypertension, an intervention to aid primary care clinician delivery of guideline-recommended care did not improve clinical outcomes.<sup>35</sup> The measure of efficacy for a CKD intervention is also important, since increasing CKD screening may not translate to increased treatment.<sup>36</sup>

Several recent implementation programs have succeeded in analogous populations. For example, the Coordinated Care to Optimize Cardiovascular Preventive Therapies in Type 2 Diabetes (COORDINATE-Diabetes) trial used a multifaceted intervention that improved prescription of guideline-based therapies among patients with type 2 diabetes and arteriosclerotic cardiovascular disease.<sup>37</sup> Electronic health record alerts with targeted recommendations improved prescription rates of guideline-recommended therapies in patients with heart failure and reduced ejection fraction.<sup>38,39</sup> To leverage our study findings to improve CKD screening, interventions could educate clinicians to continue CKD screening in people with T2D regardless of eGFR level or active ACEI or ARB use. Interventions could also emphasize the safety of SGLT2 inhibitors in people with peripheral arterial disease or lower eGFR.

### Strengths and Limitations

This study design provides numerous strengths. We analyzed granular data from over 300 000 people across 20 health systems using standardized data from the PCORnet common data model. For analysis of treatment, we tailored the inclusion criteria to approximate the study cohorts from phase 3 studies of SGLT2 inhibitors in CKD and restricted data collection to clinic visits following FDA approval for this indication. However, it is possible that choice of a later date, such as publication of

the revised KDIGO (Kidney Disease—Improving Global Outcomes) guidelines in October 2020,<sup>5</sup> would have yielded substantially higher numbers of prescriptions for SGLT2 inhibitors.

We also acknowledge limitations to the study design. Observational studies are subject to residual confounding. Electronic health record data may not capture data outside the health system, data that fall outside of structured data streams (eg, scanned results or socioeconomic data), or information that may influence the appropriateness of screening or treatment, such as a limited life expectancy. Additionally, clinicians may have ordered screening laboratory evaluations that were not collected. Billing code data may not accurately capture the severity or chronicity of disease. The COVID-19 pandemic likely altered screening and treatment patterns during the study period. For example, prescriptions for SGLT2 inhibitors and ACEIs or ARBs sharply decreased in April 2020, though prescriptions for both rebounded quickly to near-prepandemic levels. We also focused on patient-level risk factors for not receiving recommended screening or treatment for CKD. We acknowledge that system-level and clinician-level factors also play a major role and will be a key part of implementation strategies to improve care for this population.

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## Conclusions

In this cohort study, fewer than one-third of patients with T2D in a large nationally representative cohort received annual creatinine and UACR screening. Cardiovascular comorbidities, ACEI or ARB use and kidney function influenced the risk of not receiving CKD screening. Importantly, we report significant disparities in screening by race and ethnicity, especially for people of Hispanic ethnicity. In patients with CKD and albuminuria following FDA approval for SGLT2 inhibitor use for CKD, fewer than 4% were prescribed an SGLT2 inhibitor. Peripheral arterial disease decreased, and hypertension increased the likelihood of receiving CKD therapy. Lower eGFR was also associated with less ACEI or ARB and SGLT2 inhibitor prescription. These limitations in CKD screening and treatment identify areas of focus for implementation strategies to improve concordance with guideline-recommended screening and therapies for CKD.

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## ARTICLE INFORMATION

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#### SUPPLEMENT 1.

**eTable 1.** ICD Codes for T2D Diagnosis

**eTable 2.** List of Covariates for the Screening and Treatment Cohort Analyses

**eTable 3.** Statistical Methods for Exploratory and Sensitivity Analyses

**eTable 4.** Baseline Characteristics Stratified by 3 Levels of Concordance With CKD Screening Guidelines in Patients With T2D and Without Known CKD

**eTable 5.** Screening Concordance Stratified by ACEI or ARB Prescription

**eTable 6.** Association Between Clinical Factors and Concordance With CKD Screening Guidelines in Patients With T2D and Without Known CKD (Excluding Patients With Missing HbA<sub>1c</sub> Measurement)

**eTable 7.** Association Between Clinical Factors and 3 Levels of Concordance With CKD Screening Guidelines in Patients With T2D and Without Known CKD

**eTable 8.** Association Between Concordance With CKD Screening Guidelines and Subsequent Clinical Events

**eTable 9.** Association Between Concordance With CKD Screening Guidelines and Subsequent Clinical Events (Excluding Patients With Missing HbA<sub>1c</sub> Measurement)

**eTable 10.** Baseline Characteristics Stratified by UACR Eligibility for the Treatment Cohort

**eFigure 1.** Screening and Treatment Concordance With Guidelines by Index Visit Month

**eFigure 2.** Prescriptions per Month for SGLT2 Inhibitors and ACEI or ARB During the Study Period

#### SUPPLEMENT 2.

**Data Sharing Statement**