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Chronic Kidney Disease Testing Among Primary Care Patients With Type 2 Diabetes Across 24 U.S. Health Care Organizations

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Clinical guidelines for people with diabetes recommend chronic kidney disease (CKD) testing at least annually using estimated glomerular filtration rate (eGFR) and urinary albumin-to-creatinine ratio (uACR). We aimed to understand CKD testing among people with type 2 diabetes in the U.S.

## **RESEARCH DESIGN AND METHODS**

Electronic health record data were analyzed from 513,165 adults with type 2 diabetes receiving primary care from 24 health care organizations and 1,164 clinical practice sites. We assessed the percentage of patients with both one or more eGFRs and one or more uACRs and each test individually in the 1, 2, and 3 years ending September 2019 by health care organization and clinical practice site. Elevated albuminuria was defined as uACR  $\geq$ 30 mg/g.

# RESULTS

The 1-year median testing rate across organizations was 51.6% for both uACR and eGFR, 89.5% for eGFR, and 52.9% for uACR. uACR testing varied (10th–90th percentile) from 44.7 to 63.3% across organizations and from 13.3 to 75.4% across sites. Over 3 years, the median testing rate for uACR across organizations was 73.7%. Overall, the prevalence of detected elevated albuminuria was 15%. The average prevalence of detected elevated albuminuria increased linearly with uACR testing rates at sites, with estimated prevalence of 6%, 15%, and 30% at uACR testing rates of 20%, 50%, and 100%, respectively.

# CONCLUSIONS

While eGFR testing rates are uniformly high among people with type 2 diabetes, testing rates for uACR are suboptimal and highly variable across and within the organizations examined. Guideline-recommended uACR testing should increase detection of CKD.

In the U.S., one in nine adults have type 2 diabetes (1,2), and one-third of those also have chronic kidney disease (CKD), defined as decreased glomerular filtration rate (GFR) or elevated albuminuria (3–5). Most people with CKD are unaware of their condition (6,7), and, to improve identification, clinical guidelines recommend testing high-risk patients with estimated GFR (eGFR) from serum creatinine and urinary albumin-to-creatinine ratio (uACR) (8–10).

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For people with type 2 diabetes, the American Diabetes Association (ADA) recommends testing eGFR and uACR at least annually. In addition, for nonpregnant people with diabetes and hypertension, the ADA recommends the use of ACE inhibitors or angiotensin receptor blockers (ARBs) when uACR measures 30-299 mg/g and strongly recommends use when uACR is  $\geq$  300 mg/g and/or eGFR is  $<60 \text{ mL/min}/1.73 \text{ m}^2$  (10). For people with type 2 diabetes and diabetic kidney disease, the ADA recommends considering use of sodium-glucose cotransporter 2 (SGLT2) inhibitors when eGFR is  $\geq$  30 mL/min/1.73 m<sup>2</sup> and uACR is > 300 mg/g, and, to reduce the risk of cardiovascular disease, the criterion is broadened to all patients with eGFR  $\geq$  30 mL/ min/1.73 m<sup>2</sup>, which includes the large number of patients with eGFR of 30-59 mL/min/1.73 m<sup>2</sup> or eGFR  $\geq$ 60 mL/min/ 1.73 m<sup>2</sup> and uACR  $\geq$  30 mg/g. Glucagonlike peptide 1 receptor agonists (GLP-1 RA) are also noted to reduce kidney disease end points, primarily albuminuria, progression of albuminuria, and cardiovascular events in people with CKD (10-13). CKD status also helps determine evidence-based recommendations for interdisciplinary care (dietitian, pharmacist, and nephrologist) (9,10,14-16).

Although testing for CKD using eGFR and uACR is noninvasive and cost effective (17,18), rates of testing in clinical practice remain suboptimal. While most people with diabetes are tested with eGFR, only about half are tested with uACR (5,19-23). Serum creatinine testing for eGFR can be done simultaneously with hemoglobin  $A_{1c}$  (HbA<sub>1c</sub>), whereas uACR requires a urine sample. In addition, while multiple methods of testing for urine protein are used interchangeably in practice, uACR is a more standardized, sensitive, and specific measure of kidney damage recommended by guidelines for screening and management of CKD (9,10,24,25). Prior research indicates substantial variation in CKD testing across facilities within the Veterans Affairs Health Care System and among 11 primary care practices participating in a research network, but variation between and within other health care organizations is unknown (20,26).

This study evaluates patterns of CKD testing among people with type 2 diabetes in the U.S. In a population of primary care patients from 24 health care

organizations, we assessed clinical guideline-recommended eGFR and uACR testing, use of alternative urine protein tests, variation in testing across and within organizations, differences in testing by patient and organization characteristics, prevalence of detected elevated albuminuria, and risk classification of CKD.

# **RESEARCH DESIGN AND METHODS**

# **Data Source and Study Population**

The American Medical Group Association (AMGA) is a nonprofit trade association representing multispecialty medical groups and integrated health care delivery systems in the U.S. This study uses longitudinal clinical electronic health record (EHR) data from 24 geographically and EHR vendor-diverse AMGA member organizations, which were extracted, mapped, and normalized by Optum.

Using data from October 2016 to September 2019, patients were aged 18–85 years, with diagnosed type 2 diabetes in the past 2 years (October 2017–September 2019), and  $\geq$ 1 outpatient visit with a primary care physician in the past year (October 2018–September 2019). We excluded patients with evidence of hospice care, CKD stage 5, or end-stage kidney disease in the past 2 years or pregnancy in the past year (Supplementary Fig. 1).

Type 2 diabetes was defined as two or more diagnoses on an outbound claim for an outpatient visit or one or more diagnoses on the patient's problem list in the EHR. Primary care physician was defined as a billing provider with a specialty of family, internal, or geriatric medicine. Hospice care, CKD stage 5, end-stage kidney disease, and pregnancy were ascertained from diagnosis and procedure codes. Data collected in an inpatient setting were excluded. Each patient was attributed to the organization from which their EHR data were derived. Within an organization, patients were attributed to the clinical practice site (e.g., outpatient office) where the most recent encounter with a primary care physician occurred. For meaningful comparisons of sites, those with <30 attributed patients were excluded.

## CKD and Diabetes Tests and Medications

The primary CKD tests of interest in this study were eGFR and uACR. Serum

creatinine was used to estimate GFR with the Chronic Kidney Disease Epidemiology Collaboration equation (27). We had no specific information on standardization of assays for serum creatinine, but standardization had largely been achieved by clinical laboratories in 2011, before the beginning of the study period (28). For uACR, we included both guantitative and semiquantitative tests with results documented as a ratio in the EHR, as well as urine albumin concentration and urine creatinine concentration documented separately with no ratio calculated, but both tested on the same day. To understand the use of alternative urine protein tests and medications that satisfy the medical attention for nephropathy quality measure (29), we described testing for urine albumin concentration alone, urine dipstick, urine protein-to-creatinine ratio (uPCR), and prescribing of ACE inhibitor or ARB medications. HbA1c testing rates were included for comparison.

Serum creatinine for eGFR and urine dipstick are included in testing panels that are a routine part of clinical care for adults with acute and chronic medical conditions other than type 2 diabetes. While it is likely that not all testing reflects a deliberate effort by a provider for diabetes management, it nonetheless enables the opportunity for CKD detection and risk stratification and fulfills quality measures.

## Prevalence of Detected Elevated Albuminuria and Risk Classification of CKD

The relationship of uACR testing rates within the past year with prevalence of detected elevated albuminuria was described for both organizations and clinical practice sites. While lower uACR thresholds for detection have been studied (30), elevated albuminuria (uACR  $\geq$  30 mg/g) was defined using thresholds established in diabetes and kidney guidelines, which correspond to evidencebased treatment recommendations (8-10,13). Prevalence of detected elevated albuminuria was calculated both among the entire study population and restricted to patients tested with uACR. Results were presented overall and stratified by ACE inhibitor or ARB prescribing in the past year.

Patients with eGFR and uACR tested in the past year were risk-classified by CKD categories established by the Kidney Disease: Improving Global Outcomes guidelines (9). Results were stratified by ACE inhibitor or ARB prescribing in the past year and diagnosed CKD in the past 2 years.

## Patient and Organization Characteristics

Patient characteristics included patient demographics (age, sex, race, and ethnicity), sociodemographics (median household income and rural-urban commuting area, imputed using the patient's fivedigit ZIP code, smoking status, and insurance type), comorbid conditions (hypertension, atherosclerotic cardiovascular disease, heart failure, CKD, and diabetic nephropathy), and Diabetes Complications Severity Index (31). Patient demographics were identified in the EHR, and comorbid conditions were ascertained from diagnosis and procedure codes in the past 2 years.

Additional characteristics included utilization (outpatient visits for evaluation and management with any practitioner, an endocrinologist, a nephrologist, and visits for medical nutrition therapy or diabetes education), medications prescribed (ACE inhibitor or ARB, GLP-1 RA, SGLT2 inhibitor, and statins), and intermediate outcomes reflected by quality measures (blood pressure <140/90 mmHg and HbA<sub>1c</sub> <8.0%) (29,32,33). Utilization was ascertained from procedure codes and clinical specialty of the billing provider on outbound claims. Medication prescribing and utilization were ascertained in the past 2 years. Intermediate outcomes were ascertained from outpatient blood pressure measurements and HbA<sub>1c</sub> results in the past year; for those with multiple measurements, the most recent was used.

Organization type (integrated delivery system vs. multispecialty medical group) was ascertained from membership information collected by AMGA. Organization size was defined using the number of patients who qualified for the study population. Having nephrology specialists within the organization was ascertained from the presence of outbound claims for providers with a specialty listed as nephrology and confirmed on each organization's website in January 2020.

#### **Statistical Analysis**

Analyses were performed using R, version 3.6.2, and R Studio, version 1.1.383

(R Foundation for Statistical Computing, Vienna, Austria). Use of CKD and diabetes tests and medications were described as the percentage of patients with one or more tests performed or medication prescribed in the past 1 year, 2 years, and 3 years. Rates were described for each test or medication individually and specific combinations of clinical relevance. Frequencies were described using the mean and SD, based on the number of days with one or more tests in each period. The distribution of testing rates and frequencies across organizations and clinical practice sites were described using the median and 10th and 90th percentiles. For differences within organizations, we described the distribution of having one or more eGFRs and one or more uACRs in the past year, separately, across clinical practice sites within each organization.

Multivariable logistic regression was used to calculate odds of testing in the past year as a function of patient and organization characteristics, for uACR testing alone, and for both eGFR and uACR testing. To account for clustering of similar patients within organizations and sites, models were adjusted for organization, with robust SEs clustered by clinical practice site ("glm.cluster" command from the miceadds R package) (34,35). For organization characteristics, we removed organization from the patient models and included organization size, type, and nephrology employment.

# RESULTS

#### **Study Characteristics**

Among 3,976,210 adult primary care patients from 24 organizations, 513,165 patients in 1,164 clinical practice sites had type 2 diabetes and none of the exclusion criteria and were included in the study (Supplementary Table 1). Mean age was 64.1 years, and most patients were White (78.1%), with commercial (44.0%) or Medicare (46.6%) insurance (Table 1). Over half (54.2%) of the study population had both eGFR and uACR tested in the past year, and 89.5% met the medical attention for nephropathy quality measure. Among the 45.8% of patients without eGFR or uACR, 76.3% had eGFR tested, and 3.6% had uACR. Most patient characteristics did not differ markedly between patients tested for eGFR and uACR or

not, except for other laboratory tests such as HbA<sub>1c</sub> and the caveat that even small differences were statistically significant (P < 0.05), given the large sample size.

# CKD and Diabetes Tests and Medications

In the past year, the median testing rate was 51.6% for both eGFR and uACR, 89.5% for eGFR, and 52.9% for uACR, compared with 91.1% for HbA<sub>1c</sub> (Table 2). Testing rates for uACR varied (10th–90th percentile) from 44.7 to 63.3% across organizations and from 13.3 to 75.4% across clinical practice sites. Counting all tests in the past 3 years, the median testing rate across organizations was 97.1% for eGFR and 73.7% for uACR (Table 2), and the median testing frequency was 6.3 testing days for eGFR and 1.6 days for uACR (Supplementary Table 2).

Expanding the criteria to eGFR and any urine protein test in the past year resulted in a median (10th–90th percentile) testing rate of 66.4% (58.9–72.4%) across organizations and 67.0% (36.9–81.1%) across clinical practice sites (Table 2). Using eGFR and either any urine protein or an ACE inhibitor or ARB raised the median rate in the past year to 80.1% (76.8–84.9%) across organizations and 80.8% (56.6–90.1%) across clinical practice sites.

Variation in testing across organizations was small for eGFR and large for uACR. However, within most organizations, there was marked variation across clinical practice sites for both tests (Fig. 1). For eGFR testing, 17 of 24 organizations (71%) had at least 1 clinical practice site above the 90th percentile across all clinical practice sites at all organizations, and 19 of 24 (79%) had at least 1 site below the 10th percentile (Fig. 1*C*). For uACR testing, 15 of 24 (63%) had at least 1 site above the 90th percentile, and 18 of 24 (75%) had at least 1 site below the 10th percentile (Fig. 1*D*).

#### Prevalence of Detected Elevated Albuminuria and Risk Classification of CKD

Elevated albuminuria (uACR>30 mg/g) was detected in 15% of all patients with type 2 diabetes. The average prevalence of detected elevated albuminuria increased linearly with uACR testing rates at clinical practice sites, with estimated prevalence of 6%, 15%, and 30% at uACR testing rates of 20%, 50%, and 100% (Fig. 2*B*). Among

Table 1-Characteristics among all patient	s by uACR and eGFR testing	_			
	All patients	uACR and eGFR, tested	uACR or eGFR, not tested	uACR, tested	uACR, not tested
N (%)	513,165 (100)	278,309 (54.2)	284,856 (45.8)	286,823 (55.9)	226,342 (44.1)
Demographics					
Age (years), %					
18–49	12.3	11.3	13.4	11.6	13.1
50-64	35.1	35.0	35.1	35.2	34.9
65–75	34.5	36.0	32.8	35.8	32.9
76–85	18.1	17.6	18.8	17.4	19.1
Sex: female, %	48.6	48.1	49.2	48.1	49.1
Race, %					
American Indian or Alaska Native	0.4	0.4	0.4	0.4	0.4
Asian	2.7	3.0	2.3	3.0	2.3
Black or African American	12.3	12.6	11.9	12.7	11.8
White or Caucasian	78.1	77.3	79.0	77.2	79.1
Other/unknown	6.5	6.7	6.4	6.7	6.4
Ethnicity, %					
Hispanic	6.5	7.0	5.9	7.0	5.8
Not Hispanic	89.7	89.9	89.5	89.8	89.6
Unknown	3.8	3.1	4.6	3.1	4.6
RUCA, %					
Metropolitan	80.2	83.3	76.4	83.3	76.1
Large rural city	8.5	7.1	10.3	7.1	10.4
Small or isolated rural	8.6	7.3	10.2	7.3	10.3
Unknown	2.7	2.3	3.1	2.3	3.1
Median household income, median (IQR)	42,960 (35,635–54,197)	44,274 (36,334–55,235)	42,022 (34,661–52,626)	44,198 (36,334–55,235)	42,022 (34,661–52,593)
Insurance, %					
Commercial	44.0	44.8	42.9	44.9	42.7
Medicaid	4.9	4.3	5.6	4.4	5.5
Medicare	46.6	46.2	47.0	46.0	47.4
Other	4.5	4.6	4.4	4.7	4.4
Smoking, %					
Current	12.1	10.8	13.6	10.9	13.6
Previous	33.6	33.5	33.7	33.5	33.8
Never	54.3	55.7	52.7	55.6	52.6
Comorbid conditions diagnosed, %					
Hypertension	80.1	81.0	79.0	80.7	79.3
Heart failure	9.0	8.1	10.1	8.0	10.3
ASCVD	30.4	29.5	31.6	29.3	31.8
Diabetic retinopathy	1.9	2.1	1.6	2.1	1.6
CKD	25.2	27.4	22.7	27.1	22.9
DCSI, mean (SD)	2.0 (2.1)	2.0 (2.1)	2.0 (2.1)	2.0 (2.1)	2.0 (2.1)
					Continued on p. 2004

Table 1–Continued					
	All patients	uACR and eGFR, tested	uACR or eGFR, not tested	uACR, tested	uACR, not tested
Medications prescribed, %					
GLP-1 RA	12.0	13.4	10.3	13.3	10.2
SGLT2 inhibitor	11.0	12.2	9.4	12.2	9.4
Statin	73.2	7.77	68.0	77.5	67.9
ACE inhibitor or ARB	68.2	71.4	64.4	71.1	64.5
Utilization					
Diabetes education or medical nutrition, %	8.1	0.6	6.9	0.6	6.9
Outpatient visits, mean (SD)					
Any provider	13.2 (12.7)	13.7 (13.0)	12.6 (12.3)	13.6 (12.9)	12.7 (12.3)
PCP	6.7 (4.9)	6.9 (4.9)	6.5 (4.9)	6.9 (4.9)	6.5 (5.0)
Endocrinology	0.4 (1.3)	0.4 (1.5)	0.3 (1.1)	0.4 (1.5)	0.3 (1.1)
Nephrology	0.1 (0.6)	0.1 (0.7)	0.1 (0.6)	0.1 (0.7)	0.1 (0.6)
Laboratory tests					
eGFR					
Measured, %	89.1	100	76.3	97.0	79.1
Mean (SD), mL/min/1.73 m <sup>2</sup>	77.4 (22.7)	77.6 (22.2)	77.0 (23.3)	77.8 (22.1)	76.8 (23.3)
uACR					
Measured, %	55.9	100	3.6	100	0
Median (IQR), mg/g	16.0 (8.2–39.0)	16.0 (8.2–39.0)	16.1 (8.1 - 34.1)	16.0 (8.2–39.0)	
Urine albumin concentration					
Measured, %	59.2	98.6	12.5	98.4	9.6
Median (IQR), mg/dL	1.4 (1.0–4.3)	1.4 (1.0–4.3)	1.6 (1.0–5.0)	1.4 (1.0–4.3)	1.7 (0.9–5.7)
uPCR					
Measured, %	1.7	1.8	1.6	1.8	1.7
Median (IQR), mg/g	242 (120–740)	239 (121–683)	250 (123–871)	239 (121–685)	250 (120–870)
Urine dipstick: measured, %	30.6	34.4	26.1	33.9	26.5
Quality measures*					
HbA <sub>1c</sub> , %					
Missing	7.4	0.5	15.6	0.6	16.0
≥8.0% (≥7.0)	19.5 (41.8)	20.5 (45.5)	18.2 (37.3)	20.7 (45.6)	18.0 (37.0)
<8.0% (< 7.0)	73.1 (50.8)	79.0 (54.0)	66.2 (47.1)	78.7 (53.8)	66.0 (47.0)
BP, %					
Missing	0.3	0.0	0.5	0.0	0.5
≥140/90 mmHg (≥130/80)	20.8 (55.8)	19.5 (55.1)	22.5 (56.6)	19.4 (55.1)	22.6 (56.6)
<140/90 mmHg (<130/80)	78.9 (43.9)	80.5 (44.8)	77.0 (42.9)	80.5 (44.8)	76.9 (42.8)
Medical attention for nephropathy, %	89.5	100	77.1	100	76.2
ASCVD, atherosclerotic cardiovascular disease; BP, *Missing HbA $_{\rm Mc}$ is HbA $_{\rm Mc} \ge 8.0\%~(\ge 7.0),$ and HbA $_{\rm Mc}$	blood pressure; DCSI, Diab <8.0% (<7.0), sum to 100	etes Complications Severity Index $\%$ , and missing BP is BP $\geq$ 140/9	; IQR, interquartile range; PCP, prin 0 mmHg ( $\geq$ 130/80) and BP $<$ 140/9	nary care physician; RUCA, ri 00 mmHg (<130/80), sum to	ural-urban commuting area. 100%.

2004 CKD Testing in Type 2 Diabetes

Percent of patients with $\geq 1$ test or prescription in time period	Organizations (n = 24), median (10th–90th percentile), %	Clinical practice sites ( $n = 1,164$ ), median (10th–90th percentile), %
eGFR and uACR		
1 year	51.6 (44.1–61.9)	53.8 (11.9-73.4)
2 years	69.3 (54.7–78.7)	72.8 (22.7–89.7)
3 years	73.4 (57.4–82.2)	78.6 (26.7–92.3)
eGFR		
1 year	89.5 (86.2–91.6)	90.0 (70.8–95.9)
2 years	96.1 (94.8–97.6)	97.1 (86.5–99.3)
3 years	97.1 (95.7–98.5)	98.0 (88.4–99.7)
uACR		
1 year	52.9 (44.7–63.3)	55.3 (13.3–75.4)
2 years	69.7 (54.8–79.1)	73.3 (23.3–90.2)
3 years	73.7 (57.5–82.5)	78.9 (27.7–92.5)
eGFR and any urine protein test <sup>+</sup>		
1 year	66.4 (58.9–72.4)	67.0 (36.9–81.1)
2 years	82.1 (76.3–87.7)	85.2 (54.1–93.9)
3 years	86.0 (80.0–91.3)	89.2 (57.5–95.8)
Urine albumin concentration		
1 year	57.1 (44.8–63.8)	59.2 (22.3–75.8)
2 years	71.5 (58.3–80.8)	76.8 (34.0–90.6)
3 years	76.1 (61.5–84.1)	81.6 (37.1–92.8)
Urine dipstick		
1 year	31.2 (22.3–48.6)	24.7 (14.5–50.4)
2 years	43.4 (32.2–62.2)	36.3 (22.9–64.7)
3 years	51.2 (38.7–69.2)	43.8 (27.7–70.7)
uPCR		
1 year	1.3 (0.1–3.3)	1.0 (0.0–4.3)
2 years	1.8 (0.1–4.2)	1.5 (0.0–5.7)
3 years	2.1 (0.2–5.1)	1.8 (0.0–6.4)
eGFR and any urine protein or ACE inhibitor or ARB prescribing		
1 year	80.1 (76.8-84.9)	80.8 (56.6–90.1)
2 years	91.0 (88.3–93.1)	92.2 (70.8–96.9)
3 years	92.6 (90.4–95.0)	94.3 (74.4–98.0)
ACE inhibitor or ARB prescribing		
1 year	63.0 (58.2–67.0)	62.9 (44.7–73.5)
2 years	68.4 (65.8–72.0)	67.9 (52.0–77.6)
3 years	70.9 (67.7–73.7)	70.1 (54.3–79.2)
HbA <sub>1c</sub>		
1 year	91.1 (86.7–92.3)	91.7 (72.3–96.2)
2 years	95.4 (92.8–97.0)	96.7 (82.1–98.8)
3 years	96.3 (93.6–97.6)	97.4 (83.9–99.2)

# Table 2—Distribution of the rates of testing and prescribing by increasing time period across organizations and clinical practice sites

<sup>†</sup>Urine protein tests include uACR, urine albumin concentration, urine dipstick, and uPCR.

patients with uACR tested, approximately one-third of patients had elevated albuminuria regardless of the testing rate (Fig. 2*C* and *D*). Among patients with an ACE inhibitor or ARB prescribed and uACR tested,  $\sim$ 34% had elevated albuminuria compared with  $\sim$ 25% with neither medication prescribed, but there was still no relationship between uACR testing rates and the prevalence of detected elevated albuminuria (Supplementary Figs. 2*C* and *D*) and 3*C* and *D*).

Among 278,309 patients with eGFR and uACR tested in the past year, 43%

had laboratory evidence for intermediateto very-high-risk CKD, and 31% had elevated albuminuria (A2+) (Supplementary Fig. 4). Among patients with laboratory evidence for intermediate- to very-high-risk CKD, 50% had a CKD diagnosis. Among patients with elevated albuminuria, 75% had an ACE inhibitor or ARB prescribed within the past year.

# Characteristics Associated With eGFR and uACR Testing

Many patient characteristics were statistically significantly associated with having both eGFR and uACR tested (Supplementary Fig. 5). Patients living in a small rural town or isolated area (compared with metropolitan; odds ratio 0.82) and patients with Medicaid (compared with commercial; odds ratio 0.81) and Medicare insurance (odds ratio 0.90) were associated with lower testing. Hispanic (compared with non--Hispanic; odds ratio 1.13) and Asian (compared with White or Caucasian; odds ratio 1.13) patients were associated with higher testing. There was no statistically significant difference in testing for Black or African American (compared with White or Caucasian; odds



**Figure 1**—eGFR and uACR testing rates by organization and clinical practice site. Each square (*A* and *B*) reflects a different health care organization that is ranked (horizontally) in descending order of testing rate. Each set of colored circles (*C* and *D*) describe testing rates for the clinical practice sites within the respective organization with the same color in the panel directly above. Pts., patients.

ratio 1.08) and American Indian or Alaska Native (compared with White or Caucasian; odds ratio 1.02) patients. With the exception of having no HbA<sub>1c</sub> tested (odds ratio 0.03,), all associations were of modest magnitude (odds ratio 0.76-1.33) (Supplementary Figs. 5 and 6). In contrast, odds ratios by health care organizations ranged from 0.10 to 1.80 (Supplementary Fig. 7).

# CONCLUSIONS

Evaluation of CKD testing among over half a million people with type 2 diabetes who were receiving primary care from 24 health care organizations with 1,164 clinical practice sites showed suboptimal and variable adherence to guideline-recommended testing of uACR. In contrast, eGFR testing rates are uniformly high across organizations. Relaxing the eligible testing period from the past 1 to 3 years raised the median uACR testing rate across organizations from 52.9 to 73.7%, but this still leaves over one-quarter of patients in at least half of the organizations without uACR testing for the full 3year period.

We can identify several possible explanations for the higher testing rates for eGFR compared with uACR. First, serum creatinine, which is used to estimate GFR, is part of the basic and comprehensive metabolic panels commonly used in clinical care (24). This represents opportunistic testing but nonetheless enables identification and risk classification of CKD. Second, eGFR is integral for drug dosing, and many medications require monitoring of kidney function. Third, testing rates for eGFR and HbA<sub>1c</sub> were similar, suggesting the two blood tests may be performed at the same time. Fourth, urine tests generally

collected during an office visit may present logistical challenges or potential hesitation regarding additional testing for some patients. Lastly, it is possible that differences reflect historical provider and organization perceptions of the importance of testing both eGFR and uACR annually for diabetes management (e.g., some organizations may have quality benchmarks, tools in the EHR, or clinical protocols that encourage testing eGFR but not uACR).

Payers and health care organizations commonly measure quality performance with the medical attention for nephropathy measure (29), which does not include eGFR and is satisfied by any urine protein test, a prescription of an ACE inhibitor or ARB, consultation with a nephrologist, or diagnosis of CKD. ACE inhibitors and ARBs can reduce the risk of progressive kidney disease but are



**Figure 2**—Prevalence of detected elevated albuminuria ( $\geq$ 30 mg/g) and uACR testing rates among all patients (*A* and *B*) and among patients with uACR tested (*C* and *D*) by organization (*A* and *C*) and clinical practice site (*B* and *D*). Pts., patients.

also commonly prescribed to treat hypertension and do not eliminate the need for CKD testing (36). The Kidney Health Evaluation for Patients with Diabetes is a new quality measure that requires eGFR and uACR testing annually (37). In this study, 89.5% satisfied the medical attention for nephropathy criteria compared with 54.2% that satisfied the criteria for eGFR and uACR in the past year. One area for potential improvement is continued adoption of the new Kidney Health Evaluation for Patients with Diabetes measure (37,38), which could help improve adherence to guideline recommended testing. In fact, since 2020, ADA guidelines recommend monitoring eGFR and uACR twice annually in patients with diabetes and uACR >300 mg/g and/or an eGFR 30-60 mL/ min/1.73 m<sup>2</sup> (10,39).

Testing rates for uACR varied among organizations, with dramatic variation

across clinical practice sites within organizations. In comparison, differences in testing rates across patient characteristics were modest. At least half of the organizations had a site in the top (or bottom) 10% of testing across all clinical practice sites at all organizations. Higherperforming sites can be used to establish best practices for uACR testing, which can then be implemented in lower-performing sites. Organizations should analyze and benchmark performance across their own clinical practice sites, since high- and low-performing sites are not identified when combined into an overall rate for the organization.

In addition to benchmarking, supportive technology for identifying and managing CKD can help improve testing rates in primary care. One study implemented a clinical decision support tool in the EHR of 11 primary care practices and, after 2 years, found the proportion

of patients with hypertension or diabetes and annual uACR and/or uPCR testing increased from 22 to 59% (median proportion tested across practices) (20). Another study implemented a clinical decision support tool and quarterly benchmarking reports for providers at 2 organizations with a combined 60 primary care providers, and uACR testing rates increased from 43 to 65% after 1 year (40). While most EHRs already have tools with warnings and suggestions for care, our results suggest a potential opportunity to update tools to include annual CKD testing, particularly uACR.

Importantly, our study demonstrated that among all patients with type 2 diabetes, the average prevalence of detected elevated albuminuria increased linearly with uACR testing rates at clinical practice sites. Among patients with type 2 diabetes and uACR tested, roughly one in three people tested had elevated albuminuria at sites with both low and high uACR testing rates. This consistent "yield" suggests that organizations and sites with low testing rates are not preferentially testing the highest-risk patients. Overall, elevated albuminuria was detected in only 15% of all patients. With approximately half (47%) of patients with type 2 diabetes not tested, it is likely approximately half of the patients with elevated albuminuria were not detected. Increasing uACR testing should consistently increase the identification of CKD, allowing practitioners to appropriately risk stratify and tailor treatment plans to each patient's risk following ADA guidelines. Beyond improved identification, there remain opportunities for organizations to increase CKD diagnosis and management.

Our findings of high eGFR and suboptimal uACR testing are consistent with previous studies (20–23). While previous studies showed variation in CKD testing across facilities within the Veterans Affairs Health Care System and 11 primary care practices participating in a research network, our results quantify the substantial variation between and within a large national sample of health care organizations with >1,000 clinical practice sites (20,26).

This study has several strengths. First, a large sample size allowed the opportunity to describe CKD testing in populations often underrepresented in research; for example,  $\sim$ 33,000 (6.5%) patients with Hispanic ethnicity and 2,000 (0.4%), 13,000 (2.7%), and 60,000 (12.3%) patients with American Indian or Alaska Native, Asian, and Black or African American race, respectively, were included. Second, to our knowledge, this is the first large study describing CKD testing rates across and within multiple health care organizations illustrating the opportunity for increased uACR testing, broadly relevant in clinical practice to organizations of different types, sizes, and geography. Finally, patients included in the study reflect a broad and balanced representation (e.g., across commercial and Medicare health insurance and rural and urban communities).

There are several limitations to this study. First, laboratory results documented in clinical notes or scanned reports and those performed outside of the health care organization not documented in the EHR were not captured, potentially leading to underreporting of testing rates. Second, as with any observational study using data collected for purposes other than research, it is possible unmeasured characteristics were associated with CKD testing, potentially biasing odds ratios in regression models. Third, these data reflect CKD testing among U.S. multispecialty medical groups and integrated delivery systems that have focused on other quality improvement initiatives in diabetes. Thus, it is possible results may be less generalizable to other organizations. Fourth, we had no available data on which providers ordered tests or noted the results. While only tests with results documented in the EHR were included in the study, it is possible some results were never seen by the patient or their primary care provider. Lastly, diverse methodology and formats for eGFR and uACR testing and reporting may have implications for clinician interpretation and quality measurement that cannot be assessed with the available data.

Among people with type 2 diabetes, almost half of patients are not tested annually with eGFR and uACR as recommended by established clinical guidelines. While eGFR testing was high, uACR testing was performed among only one-half of patients with type 2 diabetes within 1 year and three-quarters within 3 years. Testing rates for uACR were higher among some organizations, with dramatic testing variation among clinical practice sites within every organization. Most organizations had sites with high testing rates from which to learn and sites with low testing rates that need improvement. The average prevalence of detected elevated albuminuria increased linearly with uACR testing rates. Improving uACR testing in type 2 diabetes will increase identification of patients with CKD in whom guidelines recommend more frequent patient monitoring and use of ACE inhibitor/ARB, SGLT2 inhibitor, and GLP-1 RA medications.

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#### References

1. Bullard KM, Cowie CC, Lessem SE, et al. Prevalence of diagnosed diabetes in adults by diabetes type - United States, 2016. MMWR Morb Mortal Wkly Rep 2018;67:359–361

2. Centers for Disease Control and Prevention. National Diabetes Statistics Report, 2020. Accessed 16 June 2021. Available from https:// www.cdc.gov/diabetes/data/statistics-report/index. html.

3. Afkarian M, Zelnick LR, Hall YN, et al. Clinical manifestations of kidney disease among US adults with diabetes, 1988-2014. JAMA 2016;316: 602–610

4. Spijkerman AM, Dekker JM, Nijpels G, et al. Microvascular complications at time of diagnosis of type 2 diabetes are similar among diabetic patients detected by targeted screening and patients newly diagnosed in general practice: the hoorn screening study. Diabetes Care 2003;26:2604–2608

5. Saran R, Robinson B, Abbott KC, et al. US Renal Data System 2019 Annual Data Report: Epidemiology of Kidney Disease in the United States. Am J Kidney Dis 2020;75(Suppl. 1):A6–A7 6. Coresh J, Byrd-Holt D, Astor BC, et al. Chronic kidney disease awareness, prevalence, and trends among U.S. adults, 1999 to 2000. J Am Soc Nephrol 2005:16:180–188

7. Centers for Disease Control and Prevention (CDC). Chronic Kidney Disease (CKD) Surveillance System, 2020. Accessed 16 June 2020. Available from https://nccd.cdc.gov/CKD/default.aspx

8. National Kidney Foundation. 2012 update. Am J Kidney Dis 2012;60:850–886

9. Stevens PE; Kidney Disease: Improving Global Outcomes Chronic Kidney Disease Guideline Development Work Group Members. Evaluation and management of chronic kidney disease: synopsis of the kidney disease: improving global outcomes 2012 clinical practice guideline. Ann Intern Med 2013;158:825–830

10. American Diabetes Association. 11. Microvascular complications and foot care: *Standards of Medical Care in Diabetes*—2021. Diabetes Care 2021;44(Suppl. 1):S151–S167

11. Perkovic V, Jardine MJ, Neal B, et al.; CREDENCE Trial Investigators. Canagliflozin and renal outcomes in type 2 diabetes and nephropathy. N Engl J Med 2019;380:2295–2306 12. Toyama T, Neuen BL, Jun M, et al. Effect of SGLT2 inhibitors on cardiovascular, renal and safety outcomes in patients with type 2 diabetes mellitus and chronic kidney disease: A systematic review and meta-analysis. Diabetes Obes Metab 2019;21:1237–1250

13. American Diabetes Association. 9. Pharmacologic approaches to glycemic treatment: *Standards of Medical Care in Diabetes*—2021. Diabetes Care 2021;44(Suppl. 1):S111–S124

14. Vassalotti JA, Centor R, Turner BJ, Greer RC, Choi M; National Kidney Foundation Kidney Disease Outcomes Quality Initiative. Practical approach to detection and management of chronic kidney disease for the primary care clinician. Am J Med 2016;129:153–162.e7

15. Smekal MD, Tam-Tham H, Finlay J, et al. Patient and provider experience and perspectives of a risk-based approach to multidisciplinary chronic kidney disease care: a mixed methods study. BMC Nephrol 2019;20:110

16. Vassalotti JA, DeVinney R, Lukasik S, et al. CKD quality improvement intervention with PCMH integration: health plan results. Am J Manag Care 2019;25:e326–e333

17. Hoerger TJ, Wittenborn JS, Segel JE, et al.; Centers for Disease Control and Prevention CKD Initiative. A health policy model of CKD: 2. The cost-effectiveness of microalbuminuria screening. Am J Kidney Dis 2010;55:463–473

18. Komenda P, Ferguson TW, Macdonald K, et al. Cost-effectiveness of primary screening for CKD: a systematic review. Am J Kidney Dis 2014; 63:789–797

19. Perkins RM, Chang AR, Wood KE, Coresh J, Matsushita K, Grams M. Incident chronic kidney disease: trends in management and outcomes. Clin Kidney J 2016;9:432–437

20. Litvin CB, Hyer JM, Ornstein SM. Use of clinical decision support to improve primary care identification and management of chronic kidney disease (CKD). J Am Board Fam Med 2016;29: 604–612

21. Lee J, Chu C, Guzman D, et al. Albuminuria testing by race and ethnicity among patients with hypertension with and without diabetes. Am J Nephrol 2019;50:48–54

22. Szczech LA, Stewart RC, Su HL, et al. Primary care detection of chronic kidney disease in adults with type-2 diabetes: the ADD-CKD Study (awareness, detection and drug therapy in type 2 diabetes and chronic kidney disease). PLoS One 2014;9:e110535

23. Knudsen ST, Mosbech TH, Hansen B, Kønig E, Johnsen PC, Kamper AL. Screening for microalbuminuria in patients with type 2 diabetes is incomplete in general practice. Dan Med J 2012;59:A4502

24. Miller WG, Bachmann LM, Delanghe JR, Inker LA, Jones GRD, Vassalotti JA. Optimal use of biomarkers for chronic kidney disease. Clin Chem 2019;65:949–955

25. Inker LA, Astor BC, Fox CH, et al. KDOQI US commentary on the 2012 KDIGO clinical practice guideline for the evaluation and management of CKD. Am J Kidney Dis 2014;63:713–735

26. Navaneethan SD, Akeroyd JM, Ramsey D, et al. Facility-level variations in kidney disease care among veterans with diabetes and CKD. Clin J Am Soc Nephrol 2018;13:1842–1850

27. Levey AS, Stevens LA, Schmid CH, et al.; CKD-EPI (Chronic Kidney Disease Epidemiology Collaboration). A new equation to estimate glomerular filtration rate. Ann Intern Med 2009;150:604–612

28. Miller WG, Jones GRD. Estimated glomerular filtration rate; laboratory implementation and current global status. Adv Chronic Kidney Dis 2018;25:7–13

29. Quality Payment Program, Centers for Medicare & Medicaid Services. Quality ID #119

(NQF 0062): Diabetes: Medical Attention for Nephropathy, 2020. Accessed 17 April 2020. Available from https://qpp.cms.gov/docs/QPP\_ quality\_measure\_specifications/CQM-Measures/ 2019\_Measure\_119\_MIPSCQM.pdf

30. Hayashi Y. Detection of lower albuminuria levels and early development of diabetic kidney disease using an artificial intelligence-based rule extraction approach. Diagnostics (Basel) 2019;9:133 31. Young BA, Lin E, Von Korff M, et al. Diabetes complications severity index and risk of mortality, hospitalization, and healthcare utilization. Am J Manag Care 2008;14:15–23

32. Quality Payment Program, Centers for Medicare & Medicaid Services. Quality ID #236 (NQF 0018): Controlling High Blood Pressure, 2020. Accessed 17 April 2020. Available from https://qpp.cms.gov/docs/QPP\_quality\_measure\_ specifications/CQM-Measures/2019\_Measure\_ 236\_MIPSCQM.pdf

33. National Quality Forum. Comprehensive Diabetes Care: Hemoglobin A1c (HbA1c) Control (<8.0%), 2020. Accessed 17 April 2020. Available from https://www.qualityforum.org/ QPS/Measure Details.aspx?standardID=944& print=0&entity TypeID=1

34. Robitzsch A, Grund S, Henke T. miceadds: Some Additional Multiple Imputation Functions, Especially for 'mice', 2021. Accessed 29 March 2021. Available from https://rdrr.io/cran/miceadds/ man/miceadds-package.html

35. Williams RL. A note on robust variance estimation for cluster-correlated data. Biometrics 2000;56:645–646

36. Krause TM, Ganduglia-Cazaban C, Finkel KW. Rates for HEDIS screening for diabetic nephropathy quality measure may be overstated. Manag Care 2018;27:45–49

37. National Committee for Quality Assurance (NCQA). Proposed New Measure for HEDIS 2020 Kidney Health Evaluation for Patients With Diabetes (KED), 2020. Accessed 12 August 2020. Available from https://www.ncqa.org/wp-content/ uploads/2020/02/20200212\_05\_CDC\_Nephro pathy.pdf

38. National Committee for Quality Assurance (NCQA). HEDIS Measurement Year 2020 & Measurement Year 2021, Volume 2: Summary Table of Measures, Product Lines and Changes, HEDIS Measurement Year 2020, 2020. Accessed 12 August 2020. Available from https://www. ncqa.org/wp-content/uploads/2020/07/20200 716\_Summary\_Table\_of\_Measures\_Product\_ Line\_and\_Changes\_UPDATED.pdf

39. American Diabetes Association. 11. Microvascular complications and foot care: *Standards of Medical Care in Diabetes*—2020. Diabetes Care 2020;43(Suppl. 1):S135–S151

40. MacLean CD, MacCaskey M, Littenberg B. Improving testing for proteinuria in diabetes using decision support: role of laboratory ordering systems. Lab Med 2013;44:353–357