

# Chronic Renal Insufficiency Cohort (CRIC) Study: Baseline Characteristics and Associations with Kidney Function

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**Background and objectives:** The Chronic Renal Insufficiency Cohort (CRIC) Study was established to examine risk factors for the progression of chronic kidney disease (CKD) and cardiovascular disease (CVD) in patients with CKD. We examined baseline demographic and clinical characteristics.

**Design, setting, participants, & measurements:** Seven clinical centers recruited adults who were aged 21 to 74 yr and had CKD using age-based estimated GFR (eGFR) inclusion criteria. At baseline, blood and urine specimens were collected and information regarding health behaviors, diet, quality of life, and functional status was obtained. GFR was measured using radiolabeled iothalamate in one third of participants.

**Results:** A total of 3612 participants were enrolled with mean age  $\pm$  SD of  $58.2 \pm 11.0$  yr; 46% were women, and 47% had diabetes. Overall, 45% were non-Hispanic white, 46% were non-Hispanic black, and 5% were Hispanic. Eighty-six percent reported hypertension, 22% coronary disease, and 10% heart failure. Mean body mass index was  $32.1 \pm 7.9$  kg/m<sup>2</sup>, and 47% had a BP  $>130/80$  mmHg. Mean eGFR was  $43.4 \pm 13.5$  ml/min per 1.73 m<sup>2</sup>, and median (interquartile range) protein excretion was 0.17 g/24 h (0.07 to 0.81 g/24 h). Lower eGFR was associated with older age, lower socioeconomic and educational level, cigarette smoking, self-reported CVD, peripheral arterial disease, and elevated BP.

**Conclusions:** Lower level of eGFR was associated with a greater burden of CVD as well as lower socioeconomic and educational status. Long-term follow-up of participants will provide critical insights into the epidemiology of CKD and its relationship to adverse outcomes.

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The prevalence of ESRD that requires renal replacement therapy has risen dramatically in the United States during the past three decades (1). Non-dialysis-requiring chronic kidney disease (CKD) is substantially more common than ESRD, with an estimated 15 million adults in the

United States having CKD of stage 3 or worse (as defined by an estimated GFR [eGFR] of  $<60$  ml/min per 1.73 m<sup>2</sup>) (2). Furthermore, CKD frequently progresses in severity, but the factors that are responsible for accelerated decline need further elucidation. In addition, recent studies have highlighted an important association between even mild CKD and increased risk for cardiovascular disease (CVD) (3), but the mechanisms for this association remain unclear.

In response to the epidemic of CKD and our incomplete understanding of factors that govern its progression and associated morbidity, the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) established the Chronic Renal Insufficiency Cohort (CRIC) Study in 2001. The broad

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aims of the CRIC Study are to examine risk factors for the progression of kidney disease and CVD in patients with CKD and to develop predictive models to identify high-risk subgroups. The design and methods of the CRIC Study have been previously reported (4). In this article, we characterize the eligibility and recruitment methods, describe the baseline characteristics of patients enrolled in the cohort, and report initial analyses of correlates of level of eGFR.

## Materials and Methods

### Study Organization

The CRIC Study consists of a Scientific and Data Coordinating Center; seven clinical centers, central laboratories, and reading centers; a Scientific Advisory Committee; and NIDDK project scientists as described previously (4). The study protocol was approved by institutional review boards at participating institutions, and the research was conducted in accordance with the ethical principles of the Declaration of Helsinki.

### Study Design

The CRIC Study was designed as a prospective cohort of approximately 3600 participants who were enrolled through seven clinical centers. A weighted random sample of approximately one third of the cohort (referred to as the subcohort) was assigned to undergo additional, more intensive testing (including iothalamate clearance studies to measure GFR and electron-beam tomography) that would also facilitate use of nested case-cohort substudies (4). CRIC participants are followed until death or withdrawal of informed consent. Follow-up continues even after ESRD occurs with initiation of chronic dialysis or receipt of a kidney transplant. Outcomes regarding progression of kidney dysfunction will focus principally on reductions in GFR as well as the occurrence of clinically relevant declines in renal function. Evaluation of subclinical CVD is assessed annually (*via* standard 12-lead electrocardiography and measurements of ankle-brachial index [ABI]), and transthoracic echocardiography is performed at years 1 and 4 of follow-up for all participants. Coronary artery calcium burden assessment using electron-beam tomography or multidetector computed tomography will be performed in the subcohort at years 1 and 4. Clinical cardiovascular outcomes (including acute myocardial infarction, heart failure, arrhythmias, stroke, and peripheral arterial disease [PAD]) will be ascertained every 6 mo during follow-up, and relevant medical records will be centrally adjudicated. Hypertension at entry was defined as either systolic BP  $\geq 140$  mmHg, diastolic BP  $\geq 90$  mmHg, or use of antihypertensive medications (5). Diabetes was defined as either fasting glucose  $\geq 126$  mg/dl, random glucose  $\geq 200$  mg/dl, or use of insulin or antidiabetic medication (6).

### Study Population and Recruitment

**Eligibility criteria.** The CRIC Study was designed to include a racially and ethnically diverse group of adult patients who were aged 21 to 74 yr and had mild to moderate CKD and approximately half of whom had diabetes (Table 1). The age and eGFR criteria were specifically designed to facilitate evaluation of the progression and implications of CKD across a wide spectrum of mild to moderate kidney dysfunction and age. Age-based eGFR entry criteria were established to limit the proportion of older individuals who were recruited with age-related diminutions of GFR but otherwise nonprogressive CKD. The level of eGFR used to define eligibility was based on the four-variable Modification of Diet in Renal Disease (MDRD) estimating

equation (7), using locally measured serum creatinine calibrated to the Cleveland Clinic laboratory (8).

**Exclusion criteria.** Selected exclusion criteria were implemented (Table 2). Patients with polycystic kidney disease were excluded because of its distinct pathophysiology and its exclusive focus by another ongoing NIDDK-sponsored study (9). Patients with additional primary renal diseases were excluded when active immunosuppression had been used within 6 mo of enrollment. Patients with significant coexisting illnesses were also excluded, as detailed in Table 2.

**Recruitment.** The initial protocol called for each of the seven clinical centers to enroll approximately 450 participants each during a 33-mo period (May 2003 through March 2006). In August 2005, after Hurricane Katrina, enrollment at Tulane was halted after 405 participants had been enrolled. Consequently, the recruitment period was extended and recruitment targets at the other six clinical centers were increased. Study enrollment was completed on March 31, 2007. Recruitment strategies varied from center to center and included computerized searches of laboratory databases and hand searches of medical records and referrals from health care providers.

### Screening, Enrollment, Follow-up, and Study Data Collection

A total of 5319 participants completed screening visits, at which time consent was obtained and eligibility was determined (Figure 1, Table 1). Of those screened, 4073 were found to be eligible and 3612 completed a baseline visit, defining membership in the cohort. Five individuals with an eGFR above the exclusion level completed the baseline visit in error and are included in our analyses. At the baseline visit, sociodemographic characteristics, medical history, lifestyle behaviors, and current medications were recorded. Standardized BP measurements were obtained using a previously validated protocol (10). Anthropometric measures (height, weight, and mid-abdominal waist circumference) were obtained, and body composition was assessed using bioelectrical impedance analysis techniques. ABI was measured using standard methods (11). A 12-lead electrocardiogram was obtained using standardized methods (12). GFR was assessed by the renal clearance of 125-iodine iothalamate (13) in the subcohort. As detailed in Table 1, a series of questionnaires were administered regarding quality of life, diet, cognitive function, depressive symptoms, and physical activity level. Plasma, urine, and nail samples were collected for initial study measures, and aliquots were also stored for future studies. Additional details regarding visit and contact schedule are provided in Table 1.

### Statistical Analysis

The analytical plan for the CRIC Study has been previously described (4). Baseline characteristics are described using means with SD or medians and interquartile ranges for continuous variables, and frequency distribution is described with percentages for categorical variables. Missing values occurred when a participant failed to answer a question on a case report form or when a physical measure was not obtained or a laboratory test was not performed. The analysis for each variable is based on the observed values only. Baseline characteristics are compared between groups using *t* tests, ANOVA, or  $\chi^2$  tests, as appropriate. A two-sided  $P \leq 0.05$  was considered statistically significant.

## Results

### Baseline Demographic and Clinical Characteristics of Participants

The final enrolled cohort has a mean  $\pm$  SD age of  $58.2 \pm 11.0$  yr with excellent representation of women (46%) and patients

Table 1. Sequence and schedule of CRIC Study clinic visits/contacts and procedures<sup>a</sup>

Parameter	Visit											
	Screening	Baseline	6 mo	12 mo	18 mo	24 mo	30 mo	36 mo	42 mo	48 mo	54 mo	60 mo
Type of contact	Visit	Visit	Phone	Visit	Phone	Visit	Phone	Visit	Phone	Visit	Phone	Visit
Informed consent	•											
Medical record consent				•		•		•		•		•
Contact information	•	•	•	•	•	•	•	•	•	•	•	•
Labs: creatinine, glucose	•											
Demographic information	•											
Eligibility confirmation	•											
Medical history		•		•		•		•		•		•
Genetic blood sample		•		•		•		•		•		•
Labs: CBC, metabolic panel, lipids		•		•		•		•		•		•
24-h urine		•		•		•		•		•		•
BP		•		•		•		•		•		•
Anthropometric measures		•		•		•		•		•		•
Ankle brachial index		•		•		•		•		•		•
Bioelectric impedance assessment		•		•		•		•		•		•
Nail clippings		•		•		•		•		•		•
Electrocardiogram		•		•		•		•		•		•
Echocardiogram				•						•		
EBT or MDCT (one third subcohort)				•						•		
Iothalamate-GFR (one third subcohort)		•				•				•		
Pulse wave velocity						•				•		
Physical assessment		•				•				•		
Medications		•	•	•		•		•		•		•
KDQOL quality of life (43)		•		•		•		•		•		•
Diet History Questionnaire (44)		•				•				•		
Mini Mental Status Exam (45)		•				•				•		
MDRD Symptom Index (46)		•		•		•		•		•		•
Beck Depression Inventory (47)		•				•				•		
Physical Activity (48,49)		•				•				•		
Kansas City Questionnaire (50)				•		•		•		•		•
Recent medical history		•	•	•	•	•	•	•	•	•	•	•

<sup>a</sup>CBC, complete blood count; CRIC, Chronic Renal Insufficiency Cohort; EBT, electron-beam tomography; MDCT, multidetector computed tomography; MDRD, Modification of Diet in Renal Disease; KDQOL, Kidney Disease Quality of Life.

with diabetes (47%), consistent with the targeted enrollment goals (Table 3). The cohort is racially and ethnically diverse with 1638 (45%) non-Hispanic white patients, 1651 (46%) non-Hispanic black/African American patients, 169 (5%) Hispanic patients, and 154 (4%) Asian/Pacific Islander/Native American patients. Approximately 33% of the cohort had completed a college education, and 28% had annual incomes <\$20,000 (US). Nearly 90% of the cohort had a history of hypertension. Fewer than 25% of the cohort had a self-reported history of coronary disease or PAD. Although the mean systolic and diastolic BPs were approximately 128 mmHg and approximately 71 mmHg, respectively, 47% of participants had a baseline BP >130/80 mmHg at entry. Mean body mass index (BMI) was elevated at

32.1 ± 7.9 kg/m<sup>2</sup> with more than one half of all participants having a BMI >30 kg/m<sup>2</sup>. Mean eGFR for the entire cohort was 43.4 ± 13.5 ml/min per 1.73 m<sup>2</sup>, and median (IQR) proteinuria was 0.17 g per 24 h (0.07 to 0.81 g per 24 h). Almost 70% of the cohort was taking an angiotensin-converting enzyme inhibitor or an angiotensin receptor blocker. Most participants had an eGFR consistent with National Kidney Foundation's stages 3 and 4 CKD (70 and 18%, respectively) (14).

Several differences also existed between participants with and without diabetes (Table 3). Compared with participants without diabetes, those with diabetes were more likely to be nonwhite and Hispanic and to earn annual incomes <\$20,000 but were less likely to have a college education (*P* = 0.0001).

Table 2. Eligibility and exclusion criteria

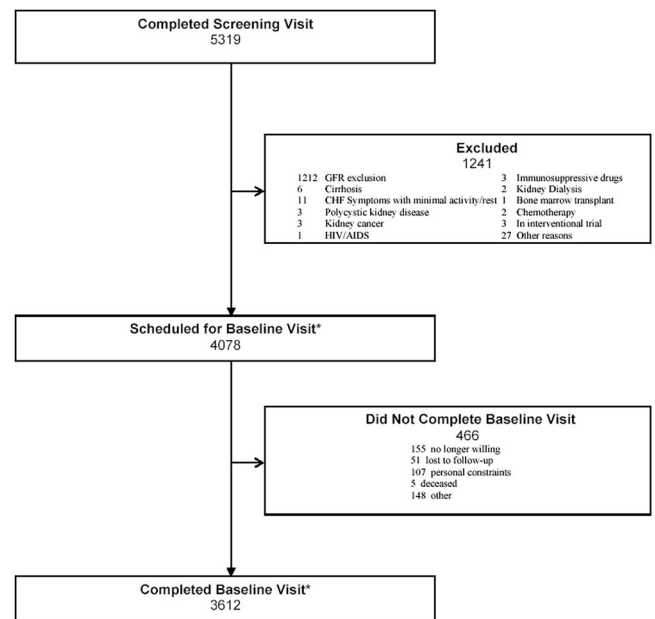
Eligibility criteria	
Age stratum (yr)/eligible eGFR range (ml/min per 1.73 m <sup>2</sup> ) <sup>a</sup>	
21 to 44/20 to 70	
45 to 64/20 to 60	
65 to 74/20 to 50	
Exclusion criteria	
institutionalized (e.g., prisoner, nursing home or skilled nursing facility resident)	
unable or unwilling to give consent	
unlikely or unable to participate in required study procedures	
New York Heart Association class III or IV heart failure (baseline)	
known cirrhosis	
known HIV infection and/or AIDS	
pregnant women	
previously received dialysis for {my}1 mo	
previous organ or bone marrow transplant	
received immunosuppressive or other immunotherapy for primary renal disease or systemic vasculitis within the past 6 mo	
previous chemotherapy or alkylating agents for systemic cancer other than non-melanoma skin cancer within 2 yr	
previous diagnosis of multiple myeloma or renal carcinoma	
polycystic kidney disease	
current participation in interventional clinical trial or in a research study	

<sup>a</sup>Based on simplified Modification of Diet in Renal Disease (MDRD) equation.

Self-reported myocardial infarction/coronary revascularization, congestive heart failure, and PAD were nearly twice as common among participants with diabetes. Participants with diabetes were also more likely to have a history of hypertension, have mean baseline BP >130/80 mmHg, and have a BMI ≥30 (*P* = 0.0001). Furthermore, these participants had a two-fold greater prevalence of an ABI <0.9. Mean eGFR was lower and urine protein higher among participants with diabetes than among those without diabetes.

*Baseline Characteristics by eGFR Level*

As a result of enrollment strategies, there was relatively even distribution by race across eGFR strata (Table 4). In comparison with those who had higher eGFR, participants with lower eGFR tended to older, female, and Hispanic (*P* = 0.0001). Also, a trend existed between lower eGFR and a higher proportion of annual incomes <\$20,000, having only high school level education, BMI >30 kg/m<sup>2</sup>, and history of >100 cigarettes. The prevalence of hypertension (and those with mean BP >130/80 mmHg), diabetes, CVD, PAD, and proteinuria were also significantly higher in lower eGFR groups (*P* = 0.0001). With



\* Five participants with eGFR above the exclusion level were scheduled and completed the baseline visit in error.

Figure 1. Participant recruitment and follow-up flow diagram. \*Five participants with estimated GFR above the exclusion level were scheduled and completed the baseline visit in error.

lower eGFR, there were progressive decreases in mean hemoglobin and increases in mean serum phosphorus and total parathyroid hormone (*P* = 0.0001).

*Select Anticipated and Actual Recruitment Targets*

Recruitment by racial and ethnic groups was similar to anticipated target goals (Table 5). In contrast, the actual recruitment of young participants with (3.99%) and without diabetes (9.51%) was less than the targeted goal of 12.5% for both subgroups (Table 6).

**Discussion**

The CRIC Study was designed to examine risk factors for CKD progression and CVD incidence and progression among a large, representative cohort of individuals with CKD. The CRIC cohort enrolled a diverse set of participants who had CKD and possessed a broad range of kidney dysfunction and other potentially important prognostic attributes. Recruitment goals regarding race/ethnicity, gender, age, and diabetes status were largely met. The strength of the CRIC Study lies in the diverse characteristics of the assembled cohort and the comprehensive data collection activities that have been designed to address gaps in our understanding of CKD-associated morbidity and mortality and to identify potential targets for trials of preventive therapies.

The baseline findings regarding diabetic status and level of kidney function support that the assembled cohort has characteristics representative of the broader CKD population. As expected, participants with diabetes in the cohort were more likely to have self-reported CVD than those without diabetes.



Table 3. Baseline demographic and clinical characteristics of participants<sup>a</sup>

Variable	Cohort (n = 3612)	Subcohort with iGFR (n = 1288)	Diabetes (n = 1683)	No Diabetes (n = 1929)	P for Diabetes versus No Diabetes
Age (yr; mean ± SD)	58.2 ± 11.0	56.1 ± 12.5	59.5 ± 9.8	57.1 ± 11.8	0.0001
Gender (n [%])					0.2516
male	1959 (54)	713 (55)	931 (55)	1028 (53)	
female	1653 (46)	575 (45)	754 (45)	899 (47)	
Racial/ethnic group (n [%])					0.0001
non-Hispanic white	1638 (45)	713 (46)	931 (39)	1028 (51)	0.2516
non-Hispanic black/ African American	1651 (46)	532 (41)	849 (50)	802 (42)	
Hispanic	169 (5)	69 (5)	111 (7)	58 (3)	
other <sup>b</sup>	154 (4)	99 (8)	76 (5)	78 (4)	0.0001
Annual household income (n [%])					0.0001
≤\$20,000	1009 (28)	297 (23)	565 (34)	444 (23)	
\$20,001 to \$50,000	906 (25)	338 (26)	432 (26)	474 (24)	
\$50,001 to \$100,000	725 (20)	306 (24)	281 (17)	444 (23)	
>\$100,000	389 (11)	153 (12)	134 (8)	255 (13)	
no response	583 (16)	193 (15)	271 (16)	312 (16)	
Educational attainment (n [%])					0.0001
<7th grade	60 (2)	16 (1)	41 (2)	19 (1)	
7th to 12th grade	545 (15)	153 (12)	319 (19)	226 (12)	
high school diploma	695 (19)	239 (19)	339 (20)	356 (18)	
vocational degree	184 (5)	64 (5)	98 (6)	86 (4)	
some college	921 (26)	319 (25)	440 (26)	481 (25)	
college graduate	696 (19)	298 (23)	281 (17)	415 (22)	
graduate degree	510 (14)	198 (15)	167 (10)	343 (18)	
Tobacco use (n [%])					
current smoker	494 (14)	151 (12)	212 (13)	282 (15)	0.0733
>100 cigarettes during lifetime	2019 (56)	667 (52)	983 (58)	1036 (54)	0.0057
Medical history (n [%])					
hypertension	3094 (86)	1091 (85)	1552 (92)	1542 (80)	0.0001
MI or coronary revascularization	810 (22)	225 (17)	493 (29)	317 (17)	0.0001
chronic heart failure	357 (10)	86 (7)	245 (15)	112 (6)	0.0001
PAD	250 (7)	80 (6)	181 (11)	69 (4)	0.0001
BP variables					
SBP (mmHg; mean ± SD)	127.7 ± 21.9	127.8 ± 21.3	132.4 ± 22.5	123.6 ± 20.5	0.0001
DBP (mmHg; mean ± SD)	71.4 ± 12.8	72.4 ± 12.7	69.4 ± 12.9	73.1 ± 12.8	0.0001
MAP (mmHg; mean ± SD)	90.2 ± 13.8	90.9 ± 13.2	90.4 ± 13.9	89.9 ± 13.6	0.3113
BP >130/80 mmHg (n [%])	1686 (47)	626 (49)	882 (53)	804 (42)	0.0001
Weight (kg; mean ± SD)	92.0 ± 23.7	89.9 ± 21.2	97.7 ± 24.2	87.1 ± 22.1	0.0001
BMI (kg/m <sup>2</sup> ; mean ± SD)	32.1 ± 7.9	31.3 ± 7.0	34.1 ± 8.2	30.3 ± 7.2	0.0001
BMI (kg/m <sup>2</sup> ; n [%])					0.0001
<25.0	607 (17)	234 (18)	179 (11)	428 (22)	
25.0 to 29.9	1017 (28)	380 (30)	388 (23)	629 (33)	0.0001
>30.0	1987 (55)	673 (52)	1118 (67)	869 (45)	
ABI<0.9 (n [%])	526 (15)	173 (14)	335 (20)	191 (10)	0.0001
Kidney function measures					
adjusted serum creatinine (mg/dl; mean ± SD)	1.73 ± 0.57	1.68 ± 0.56	1.80 ± 0.56	1.66 ± 0.56	0.0001
eGFR (ml/min/1.73 m <sup>2</sup> ; mean ± SD)	43.4 ± 13.5	45.2 ± 14.1	41.4 ± 12.9	45.1 ± 13.8	0.0001
eGFR (ml/min/1.73 m <sup>2</sup> ; n [%])					0.0001
<15	3 (0)	2 (0)	1 (0)	2 (0)	
15 to 29	664 (18)	206 (16)	351 (21)	313 (16)	
30 to 59	2532 (70)	887 (69)	1197 (71)	1335 (70)	
60 to 89	389 (11)	187 (15)	126 (8)	263 (14)	
>90	8 (0)	4 (0)	4 (0)	4 (0)	
urine protein/24 h (g; median [IQR])	0.17 (0.07 to 0.81)	0.18 (0.07 to 0.90)	0.32 (0.09 to 1.49)	0.11 (0.06 to 0.43)	0.0001
ACEI or ARB therapy (n [%])	2462 (68)	880 (68)	1336 (79)	1126 (58)	0.0001
Lipoproteins (mg/dl; mean ± SD)					
total cholesterol	183.0 ± 44.5	183.8 ± 47.1	177.0 ± 47.2	188.2 ± 41.3	0.0001
LDL cholesterol	102.5 ± 35.0	103.4 ± 36.6	96.4 ± 36.4	107.8 ± 33.7	0.0001
HDL cholesterol	48.1 ± 15.6	47.5 ± 15.7	45.7 ± 13.9	50.2 ± 16.8	0.0001
triglycerides	154.2 ± 115.6	152.2 ± 112.5	166.2 ± 130.3	143.6 ± 99.8	0.0001
Hemoglobin (g/dl; mean ± SD)	12.7 ± 1.8	12.6 ± 1.7	12.1 ± 1.7	13.2 ± 1.7	0.0001
Serum calcium (mg/dl; mean ± SD)	9.2 ± 0.5	9.2 ± 0.5	9.1 ± 0.5	9.2 ± 0.5	0.0001
Serum phosphorus (mg/dl; mean ± SD)	3.7 ± 0.7	3.7 ± 0.7	3.9 ± 0.7	3.6 ± 0.6	0.0001
Total PTH (pg/ml; median [IQR])	53.0 (34.0 to 88.0)	52.9 (34.0 to 85.0)	60.0 (37.1 to 102.4)	48.5 (32.5 to 78.0)	0.0001
Blood glucose (mg/dl; median [IQR])	97.0 (86.0 to 124.0)	97.0 (86.0 to 121.0)	127.0 (100.0 to 163.0)	90.0 (84.0 to 98.0)	0.0001
Glycosylated hemoglobin (%; mean ± SD)	6.6 ± 1.6	6.6 ± 1.6	7.7 ± 1.7	5.7 ± 0.5	0.0001

<sup>a</sup>ABI, ankle-brachial index; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; DBP, diastolic BP; eGFR, estimated GFR; iPTH, intact parathyroid hormone; IQR, interquartile range; MAP, mean arterial pressure; MI, myocardial infarction; PAD, peripheral arterial disease; SBP, systolic BP.

<sup>b</sup>Includes Asian/Pacific Islander and Native American individuals.

Table 4. Baseline characteristics by eGFR level

Variable	eGFR (ml/min per 1.73 m <sup>2</sup> )					P
	<30	30 to <40	40 to <50	50 to <60	≥60	
<i>n</i>	667	844	968	720	397	
Age (yr; mean ± SD)	58.7 ± 11.2	59.6 ± 11.0	60.0 ± 10.4	57.7 ± 10.1	51.5 ± 11.0	0.0001
Gender ( <i>n</i> [%])						0.0001
male	311 (47)	440 (52)	568 (59)	406 (56)	226 (57)	
female	356 (53)	404 (48)	400 (41)	314 (44)	171 (43)	
Racial/ethnic group ( <i>n</i> [%])						0.0673
non-Hispanic white	277 (42)	386 (46)	461 (48)	348 (48)	160 (40)	
non-Hispanic black/African American	303 (45)	387 (46)	430 (44)	319 (44)	202 (51)	
Hispanic	55 (8)	43 (5)	32 (3)	21 (3)	18 (5)	
other <sup>a</sup>	32 (5)	28 (3)	45 (5)	32 (4)	17 (4)	0.0001
Annual household income ( <i>n</i> [%])						0.1435
≤\$20,000	249 (37)	292 (35)	232 (24)	155 (22)	72 (18)	
\$20,001 to \$50,000	179 (27)	199 (24)	267 (28)	162 (23)	96 (24)	
\$50,001 to \$100,000	103 (17)	150 (18)	187 (19)	171 (24)	108 (27)	
>\$100,000	38 (6)	69 (8)	117 (12)	115 (16)	49 (12)	
no response	93 (14)	134 (16)	165 (17)	117 (16)	72 (18)	
Educational attainment ( <i>n</i> [%])						0.0001
<7th grade	27 (4)	15 (2)	10 (1)	4 (1)	2 (1)	
7th to 12th grade	126 (18)	160 (19)	143 (15)	82 (11)	27 (7)	
high school diploma	145 (22)	177 (21)	189 (20)	112 (16)	69 (17)	
vocational degree	36 (5)	38 (5)	48 (5)	36 (5)	26 (7)	
some college	162 (24)	224 (27)	228 (24)	192 (27)	112 (28)	
college graduate	106 (16)	146 (17)	188 (19)	172 (24)	82 (21)	
graduate degree	65 (10)	84 (10)	162 (17)	122 (17)	76 (19)	
Tobacco use ( <i>n</i> [%])						0.0001
current smoker	110 (16)	122 (15)	117 (12)	84 (12)	54 (14)	0.0001
>100 cigarettes during lifetime	405 (61)	500 (59)	542 (56)	375 (52)	139 (48)	0.0189
Medical history ( <i>n</i> [%])						0.0001
hypertension	612 (92)	767 (91)	848 (88)	587 (82)	267 (67)	0.0001
diabetes	352 (53)	459 (54)	448 (46)	290 (40)	130 (33)	0.0001
MI or coronary revascularization	170 (26)	227 (27)	227 (23)	131 (18)	51 (13)	0.0001
chronic heart failure	97 (15)	103 (12)	91 (10)	43 (6)	19 (5)	0.0001
PAD	75 (11)	85 (10)	47 (5)	31 (4)	11 (4)	0.0001
BP variables						
SBP (mmHg; mean ± SD)	130.5 ± 23.6	129.4 ± 23.2	127.7 ± 21.3	125.4 ± 20.2	123.5 ± 20.0	0.0001
DBP (mmHg; mean ± SD)	69.9 ± 13.3	70.0 ± 12.6	71.5 ± 12.7	72.3 ± 12.3	74.9 ± 12.8	0.0001
MAP (mmHg; mean ± SD)	90.1 ± 14.4	89.8 ± 14.0	90.2 ± 13.7	90.0 ± 13.1	91.1 ± 13.6	0.6042
BP >130/80 (mmHg; <i>n</i> [%])	335 (50)	394 (47)	466 (48)	319 (45)	164 (42)	0.0001
Weight (kg; mean ± SD)	89.8 ± 24.8	92.3 ± 23.2	92.5 ± 23.3	93.3 ± 24.1	92.4 ± 22.6	0.0311
BMI (kg/m <sup>2</sup> ; mean ± SD)	31.9 ± 8.4	32.5 ± 7.9	32.1 ± 7.8	32.2 ± 8.1	31.3 ± 7.1	0.2313
BMI category (kg/m <sup>2</sup> ; <i>n</i> [%])						0.9367
<25.0	134 (20)	128 (15)	150 (15)	121 (17)	74 (19)	
25.0 to 29.9	182 (27)	238 (28)	275 (28)	206 (29)	112 (28)	0.0001
>30	353 (53)	480 (57)	544 (56)	392 (55)	212 (54)	
ABI <0.9	142 (22)	149 (18)	125 (13)	93 (13)	15 (4)	0.0001
Roche adjusted creatinine (mean ± SD)	2.56 ± 0.56	1.90 ± 0.32	1.56 ± 0.23	1.32 ± 0.20	1.14 ± 0.20	0.0001
Urine protein/24 h (g; median [IQR])	0.58 (0.15 to 2.14)	0.26 (0.08 to 1.22)	0.13 (0.07 to 0.60)	0.10 (0.06 to 0.36)	0.10 (0.06 to 0.22)	0.0001
Lipoproteins						
total cholesterol (mg/dl; mean ± SD)	183.3 ± 51.2	182.5 ± 46.2	183.1 ± 42.1	183.2 ± 41.3	183.5 ± 39.6	0.8297
LDL cholesterol (mg/dl; mean ± SD)	99.7 ± 37.9	100.2 ± 35.3	103.1 ± 34.6	104.4 ± 33.3	107.3 ± 32.6	0.0001
HDL cholesterol (mg/dl; mean ± SD)	46.9 ± 15.5	47.4 ± 15.8	48.2 ± 14.9	48.8 ± 16.0	50.2 ± 16.4	0.0004
triglycerides (mg/dl; mean ± SD)	168.1 ± 127.2	163.0 ± 123.4	151.4 ± 99.6	148.5 ± 127.2	129.9 ± 81.6	0.0001
Hemoglobin (g/dl; mean ± SD)	11.8 ± 1.7	12.3 ± 1.7	12.8 ± 1.7	13.2 ± 1.6	13.4 ± 1.6	0.0001
Serum calcium (mg/dl; mean ± SD)	9.1 ± 0.6	9.2 ± 0.5	9.2 ± 0.5	9.2 ± 0.5	9.2 ± 0.4	0.0002
Total iPTH (pg/ml; median [IQR])	105.0 (64.0 to 172.0)	63.9 (41.0 to 100.0)	47.5 (32.0 to 74.0)	41.0 (29.7 to 59.1)	36.0 (27.3 to 50.3)	0.0001
Serum phosphorus (mg/dl; mean ± SD)	4.1 ± 0.8	3.8 ± 0.6	3.6 ± 0.6	3.5 ± 0.6	3.4 ± 0.5	0.0001
Blood glucose (mg/dl; median [IQR])	97.0 (85.0 to 124.0)	98.0 (87.0 to 131.0)	100.0 (88.0 to 127.0)	95.0 (85.0 to 119.0)	94.0 (84.0 to 110.0)	0.0003
Glycosylated hemoglobin (%; mean ± SD)	6.7 ± 1.5	6.8 ± 1.6	6.7 ± 1.5	6.5 ± 1.4	6.3 ± 1.7	0.0001
Serum uric acid (mg/dl; mean ± SD)	8.2 ± 2.0	7.9 ± 1.9	7.3 ± 1.8	6.8 ± 1.6	6.2 ± 1.7	0.0001

<sup>a</sup>Includes Asian/Pacific Islander and Native American individuals.

Table 5. Select anticipated and actual recruitment targets: Race/ethnic target distribution in CRIC Study

Race/Ethnic Group	Anticipated (%)	Actual (%)
Non-Hispanic white	47.50	45.34
Non-Hispanic black	47.50	45.92
Other <sup>a</sup>	5.00	8.75

<sup>a</sup>For the purposes of recruitment goal, other group includes Hispanic, Asian/Pacific Islander, and Native American individuals.

Table 6. Select anticipated and actual recruitment targets: Age- and diabetes-status distribution in CRIC Study

Age Stratum (yr)	Anticipated Recruitment (%)		Actual Recruitment Cohort (%)	
	No Diabetes	Diabetes	No Diabetes	Diabetes
21 to 44	12.50	12.50	9.51	3.99
45 to 64	25.00	25.00	29.72	27.75
65 to 74	12.50	12.50	14.56	14.47

The findings in the CRIC subgroup with diabetes reinforce the findings from clinical trials that indicate that the CVD burden in the ESRD population with diabetes has its beginnings earlier during the course of CKD (15,16). In addition, lower levels of eGFR were associated with a greater burden of CVD. This is consistent with the increasing evidence for the presence and severity of CKD as an independent and graded risk factor for CVD events (3). By using sophisticated measurements of kidney function and subclinical CVD, the CRIC Study will provide insights into the pathophysiology of this relationship and will enable an assessment of both traditional and nontraditional risk factors.

Noteworthy is the high prevalence of several potentially modifiable risk factors in this CKD cohort. Almost half of all participants had a BP level above the recommended goal (17). Suboptimal levels of BP control have been reported in other CKD cohorts (18,19), and the findings in the CRIC cohort reinforce the need to raise awareness of effective BP management in CKD as a public health priority. As well, we observed a high prevalence of obesity among participants with and without diabetes. It has been suggested that higher BMI may be an independent risk factor for CKD (20–22) and progression to ESRD that requires dialysis (23). The modest association between lower eGFR and previous cigarette exposure is consistent with the previously described association of smoking with CKD (24). This relationship is also of particular interest because it may represent another potential risk factor. Longitudinal follow-up of CRIC participants will afford a more rigorous assessment of these newly recognized but less studied risk factors on CVD and CKD outcomes.

We also observed an important association between lower eGFR and both lower socioeconomic status (SES) and lesser educational attainment. It is known that lower SES is associated with ESRD (25,26). Analyses of several cohorts found an association between lower SES and progressive CKD (27–29). The CRIC Study will facilitate evaluation of the impact of SES and educational level in individuals with more advanced stages of CKD and potential mediating pathways that could have important health policy implications.

Previous epidemiologic studies of the relationship between CKD and CVD have come from various sources, including *post hoc* analyses of clinical trials (30–33), large cohort studies focused on non-CKD populations (34–37), and analyses of large datasets from major health care providers (3,38). Despite the important contributions made by these studies, major gaps in our knowledge remain. The CRIC Study will occupy a unique niche because of its use of observational epidemiology in a large cohort of patients with CKD and its use of longitudinal state-of-the-art measurements of kidney function and subclinical CVD. In addition to examining risk factors for CKD and CVD progression, the CRIC Study will facilitate the development of predictive models that identify high-risk groups; the determination of exposure–outcome relationships; and the evaluation of the impact of CKD and progressive CKD on quality of life, functional status, and resource use. Unlike most previous studies, the CRIC Study continues to follow participants after progression to ESRD, thereby providing an important opportunity to study the critical period when patients transition from CKD to ESRD.

Concurrent with the CRIC Study, several ongoing studies are examining risk factors for CKD. The National Health and Nutrition Examination Survey (NHANES) monitors CKD prevalence and risk factors over time (2,39). The National Kidney Foundation's Kidney Evaluation Education Program (KEEP) collects data characterizing CKD in the community among at-risk subgroups (40). The African American Study of Kidney Disease and Hypertension (AASK) (41) is investigating factors that influence CKD progression among black individuals with hypertensive kidney disease. Internationally, the CKD-Japan Cohort Study (CKD-JAC) is in the early stages of follow-up. The information gained from the CRIC Study will be complementary to and extend the important work accomplished by these studies. As an example, compared with the population-based NHANES CKD cohort (2), the CRIC cohort is older and by design has more advanced CKD with more even distribution across eGFR strata, a larger percentage of individuals with diabetes, and a larger representation of black participants to facilitate more robust subgroup analyses.

As with all prospective observational studies, inferences regarding causality will be limited by potential biases and residual confounding. Numerous methodologic strategies have been adopted to minimize these limitations and enhance the robustness of etiologic inferences drawn from this study. Another potential limitation is underrepresentation of young individuals with diabetes. To adapt to this, this group was oversampled for recruitment into the subcohort from which more detailed assessments of kidney function and cardiovascular health will

be obtained. In addition, the less-than-anticipated recruitment of Hispanic individuals will be addressed by the ongoing supplemental recruitment of >330 Hispanic participants at the University of Illinois at Chicago.

The observed low level of proteinuria could also have potential implications for future risk of cardiovascular and renal events; however, the high prevalence of self-reported comorbidities suggests that the cohort is at increased risk for adverse events. Furthermore, in the AASK, there was significant progression of CKD despite relatively low levels of baseline proteinuria (42). It is also important to note that findings from the CRIC Study may not be generalizable to certain types of kidney disease that was poorly represented in the cohort, such as glomerulonephritis. It was not intended for the study to be representative of all patients with CKD; rather, it was designed to be broadly representative of the ESRD population in which diabetes and hypertension are reported as the primary diagnoses for >70% of patients (1). Finally, analyses included self-reported comorbidities, which are subject to inherent limitations with regard to accuracy.

The CRIC Study has assembled a large and diverse CKD cohort with characteristics that are generalizable to CKD populations managed in different practice settings in the United States. Analogous to the Framingham Heart and Atherosclerosis Risk in Communities Studies, the CRIC Study will use observational epidemiology to answer key questions about the cause, prognosis, management, clinical outcomes, health service use, and quality of life in CKD. The knowledge generated from the CRIC Study will lead to the formulation of hypotheses regarding potentially modifiable pathways that will serve as the basis for targeted interventional trials that focus on reducing the burden of CKD and CVD.

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## Disclosures

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## Erratum

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Notice of correction for Lash et al.: **Chronic Renal Insufficiency Cohort (CRIC) Study: Baseline Characteristics and Associations with Kidney Function**. August 2009(8) 1302–1311. The authors have noted two minor corrections in the text of this paper.

Page 1305, left column, second paragraph, under “Baseline

Characteristics by eGFR level”, line 3, p value should read  $\leq 0.001$  instead of 0.0001.

Page 1305, right column, second paragraph, under “Select Anticipated and Actual Recruitment Targets”, line 4, in parenthesis, should read 9.55% instead of 9.51%.

Minor changes to tables 3-6 are shown on pages 2549–2553.

**Table 3. Baseline demographic and clinical characteristics of participants**

Variable	Cohort (n = 3612)	Subcohort with iGFR (n = 1288)	Diabetic (n = 1683)	Non-diabetic (n = 1929)	P for Diabetes <i>versus</i> No Diabetes
Age (yr; mean ± SD)	58.2 ± 11.0	56.1 ± 12.5	59.5 ± 9.8	57.1 ± 11.8	0.0001
Gender (n [%])					0.2516
male	1959 (54)	713 (55)	931 (55)	1028 (53)	
female	1653 (46)	575 (45)	754 (45)	899 (47)	
Racial/ethnic group (n [%])					0.0001
non-Hispanic white	1638 (45)	588 (46)	649 (39)	989 (51)	
non-Hispanic black/African American	1651 (46)	532 (41)	849 (50)	802 (42)	
Hispanic	169 (5)	69 (5)	111 (7)	58 (3)	
other <sup>a</sup>	154 (4)	99 (8)	76 (5)	78 (4)	
Annual household income (n [%])					0.0001
≤\$20,000	1009 (28)	297 (23)	565 (34)	444 (23)	
\$20,001 to \$50,000	906 (25)	338 (26)	432 (26)	474 (25)	
\$50,001 to \$100,000	725 (20)	306 (24)	281 (17)	444 (23)	
>\$100,000	389 (11)	154 (12)	136 (8)	253 (13)	
no response	583 (16)	193 (15)	271 (16)	312 (16)	
Educational attainment (n [%])					0.0001
<7th grade	60 (2)	16 (1)	41 (2)	19 (1)	
7th to 12th grade	545 (15)	153 (12)	319 (19)	226 (12)	
high school diploma	695 (19)	239 (19)	339 (20)	356 (18)	
vocational degree	184 (5)	64 (5)	98 (6)	86 (4)	
some college	921 (26)	319 (25)	440 (26)	481 (25)	
college graduate	696 (19)	298 (23)	281 (17)	415 (22)	
graduate degree	510 (14)	198 (15)	167 (10)	343 (18)	
Tobacco use (n [%])					0.0733
current smoker	494 (14)	152 (12)	212 (13)	282 (15)	
>100 cigarettes during lifetime	2019 (56)	667 (52)	983 (58)	1036 (54)	0.0057
Medical history (n [%])					0.0001
hypertension	3094 (86)	1091 (85)	1552 (92)	1542 (80)	
MI or coronary revascularization	810 (22)	225 (17)	493 (29)	317 (16)	0.0001
chronic heart failure	357 (10)	86 (7)	245 (15)	112 (6)	0.0001
PAD	250 (7)	80 (6)	181 (11)	69 (4)	0.0001
BP variables					0.0001
SBP (mmHg; mean ± SD)	127.7 ± 21.9	127.8 ± 21.3	132.4 ± 22.5	123.6 ± 20.5	
DBP (mmHg; mean ± SD)	71.4 ± 12.8	72.4 ± 12.7	69.4 ± 12.8	73.1 ± 12.6	0.0001
MAP (mmHg; mean ± SD)	90.2 ± 13.8	90.9 ± 13.2	90.4 ± 13.9	89.9 ± 13.6	0.3113
BP >130/80 mmHg (n [%])	1686 (47)	626 (49)	882 (53)	804 (42)	0.0001
Weight (kg; mean ± SD)	92.0 ± 23.7	89.9 ± 21.2	97.7 ± 24.2	87.1 ± 22.1	0.0001
BMI (kg/m <sup>2</sup> ; mean ± SD)	32.1 ± 7.9	31.3 ± 7.0	34.1 ± 8.2	30.3 ± 7.2	0.0001



Variable	Cohort (n = 3612)	Subcohort with iGFR (n = 1288)	Diabetic (n = 1683)	Nondiabetic (n = 1929)	P for Diabetes <i>versus</i> No Diabetes
BMI category (kg/m <sup>2</sup> ; n [%])					0.0001
<25.0	607 (17)	234 (18)	179 (11)	428 (22)	
25.0 to 29.9	1018 (28)	381 (30)	388 (23)	630 (33)	
≥30	1987 (55)	673 (52)	1118 (66)	869 (45)	
ABI <0.9 (n [%])	584 (16)	194 (15)	371 (23)	213 (11)	0.0001
Kidney function measures					
adjusted serum creatinine (mg/dl; mean ± SD)	1.73 ± 0.57	1.68 ± 0.56	1.80 ± 0.56	1.67 ± 0.57	0.0001
eGFR (ml/min/1.73 m <sup>2</sup> ; mean ± SD)	43.4 ± 13.5	45.2 ± 14.1	41.4 ± 12.9	45.1 ± 13.8	0.0001
eGFR (ml/min/1.73 m <sup>2</sup> ; n [%])					
<15	3 (0)	2 (0)	1 (0)	2 (0)	0.0001
15 to 29	664 (18)	206 (16)	351 (21)	313 (16)	
30 to 59	2532 (70)	887 (69)	1197 (71)	1335 (70)	
60 to 89	389 (11)	187 (15)	126 (8)	263 (14)	
>90	8 (0)	4 (0)	4 (0)	4 (0)	
urine protein/24 h (g; median [IQR])	0.17 (0.07 to 0.81)	0.18 (0.07 to 0.90)	0.32 (0.09 to 1.49)	0.11 (0.06 to 0.43)	0.0001
ACEI or ARB therapy (n [%])	2462 (68)	880 (68)	1336 (79)	1126 (58)	0.0001
Lipoproteins (mg/dl; mean ± SD)					
total cholesterol	183.1 ± 44.5	183.6 ± 47.0	177.0 ± 47.1	188.4 ± 41.5	0.0001
LDL cholesterol	102.6 ± 35.3	103.4 ± 36.5	96.4 ± 35.4	108.1 ± 34.2	0.0001
HDL cholesterol	48.1 ± 15.6	47.5 ± 15.7	45.7 ± 13.9	50.2 ± 16.8	0.0001
triglycerides	153.7 ± 115.2	151.5 ± 111.9	166.0 ± 129.8	142.9 ± 99.3	0.0001
Hemoglobin (g/dl; mean ± SD)	12.7 ± 1.8	12.6 ± 1.7	12.1 ± 1.7	13.2 ± 1.7	0.0001
Serum calcium (mg/dl; mean ± SD)	9.2 ± 0.5	9.2 ± 0.5	9.1 ± 0.5	9.2 ± 0.5	0.0001
Serum phosphorus (mg/dl; mean ± SD)	3.7 ± 0.7	3.7 ± 0.7	3.9 ± 0.7	3.5 ± 0.6	0.0001
Total iPTH (pg/ml; median [IQR])	53.0 (34.0 to 88.0)	52.9 (34.0 to 85.0)	60.0 (37.1 to 102.4)	48.5 (32.5 to 78.0)	0.0001
Blood glucose (mg/dl; median [IQR])	97.0 (86.0 to 124.0)	97.0 (86.0 to 121.0)	127.0 (100.0 to 163.0)	90.0 (84.0 to 98.0)	0.0001
Glycosylated hemoglobin (%; mean ± SD)	6.6 ± 1.6	6.5 ± 1.6	7.7 ± 1.7	5.7 ± 0.5	0.0001

ABI, ankle-brachial index; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; DBP, diastolic BP; eGFR, estimated GFR; iPTH, intact parathyroid hormone; IQR, interquartile range; MAP, mean arterial pressure; MI, myocardial infarction; PAD, peripheral arterial disease; SB, systolic BP.  
 a Includes Asian/Pacific Islanders, and Native American individuals.

**Table 4. Baseline characteristics by eGFR level**

Variable	eGFR (ml/min per 1.73m <sup>2</sup> )					P
	<30	30 to <40	40 to <50	50 to <60	≥60	
<i>n</i>	667	844	968	720	397	
Age (yr; mean ± SD)	58.7 ± 11.2	59.6 ± 11.0	60.0 ± 10.4	57.7 ± 10.1	51.5 ± 11.0	0.0001
Gender ( <i>n</i> [%])						0.0001
male	311 (47)	440 (52)	568 (59)	406 (56)	226 (57)	
female	356 (53)	404 (48)	400 (41)	314 (44)	171 (43)	
Racial/ethnic group ( <i>n</i> [%])						0.0012
non-Hispanic white	277 (42)	386 (46)	461 (48)	348 (48)	160 (40)	
non-Hispanic black/African American	303 (45)	387 (46)	430 (44)	319 (44)	202 (51)	
Hispanic	55 (8)	43 (5)	32 (3)	21 (3)	18 (5)	
Other <sup>a</sup>	32 (5)	28 (3)	45 (5)	32 (4)	17 (4)	
Annual household income ( <i>n</i> [%])						0.0001
≤\$20,000	249 (37)	292 (35)	232 (24)	155 (22)	72 (18)	
\$20,001 to \$50,000	179 (27)	199 (24)	267 (28)	162 (23)	96 (24)	
\$50,001 to \$100,000	108 (16)	150 (18)	187 (19)	171 (24)	108 (27)	
>\$100,000	38 (6)	69 (8)	117 (12)	115 (16)	49 (12)	
no response	93 (14)	134 (16)	165 (17)	117 (16)	72 (18)	
Educational attainment ( <i>n</i> [%])						0.0001
<7th grade	27 (4)	15 (2)	10 (1)	4 (1)	4 (1)	
7th to 12th grade	126 (19)	160 (19)	143 (15)	82 (11)	27 (7)	
high school diploma	145 (22)	177 (21)	189 (20)	112 (16)	69 (17)	
vocational degree	36 (5)	38 (5)	48 (5)	36 (5)	26 (7)	
some college	162 (24)	224 (27)	228 (24)	192 (27)	112 (28)	
college graduate	106 (16)	146 (17)	188 (19)	172 (24)	82 (21)	
graduate degree	65 (10)	84 (10)	162 (17)	122 (17)	76 (19)	
Tobacco use ( <i>n</i> [%])						0.01
current smoker	110 (16)	123 (15)	117 (12)	84 (12)	54 (14)	
>100 cigarettes during lifetime	405 (61)	500 (59)	542 (56)	375 (52)	189 (48)	0.0001
Medical history ( <i>n</i> [%])						0.0001
hypertension	612 (92)	767 (91)	848 (88)	587 (82)	267 (67)	0.0001
diabetes	352 (53)	459 (54)	448 (46)	290 (40)	130 (33)	0.0001
MI or coronary revascularization	170 (25)	227 (27)	227 (23)	131 (18)	51 (13)	0.0001
chronic heart failure	97 (15)	103 (12)	91 (9)	43 (6)	19 (5)	0.0001
PAD	75 (11)	85 (10)	47 (5)	31 (4)	11 (3)	0.0001
BP variables						0.0001
SBP (mmHg; mean ± SD)	130.5 ± 23.6	129.4 ± 23.2	127.7 ± 21.3	125.4 ± 20.2	123.5 ± 20.0	0.0001
DBP (mmHg; mean ± SD)	69.9 ± 13.3	70.0 ± 12.6	71.5 ± 12.7	72.3 ± 12.3	74.9 ± 12.8	0.0001
MAP (mmHg; mean ± SD)	90.1 ± 14.4	89.8 ± 14.0	90.2 ± 13.7	90.0 ± 13.1	91.1 ± 13.7	0.574
BP >130/80 (mmHg; <i>n</i> [%])	335 (50)	394 (47)	466 (48)	319 (45)	164 (42)	0.0004
Weight (kg; mean ± SD)	89.8 ± 24.8	92.3 ± 23.2	92.5 ± 23.3	93.3 ± 24.1	92.3 ± 22.6	0.0311
BMI (kg/m <sup>2</sup> ; mean ± SD)	31.9 ± 8.4	32.5 ± 7.9	32.1 ± 7.8	32.2 ± 8.1	31.3 ± 7.1	0.2129

**Table 4. (Continued)**

Variable	eGFR (ml/min per 1.73m <sup>2</sup> )					P
	<30	30 to <40	40 to <50	50 to <60	≥60	
BMI category (kg/m <sup>2</sup> ; n [%])						0.9501
<25	132 (20)	126 (15)	149 (15)	121 (17)	73 (18)	
25 to 29.9	182 (27)	238 (28)	275 (28)	207 (29)	112 (28)	
≥30	353 (53)	480 (57)	544 (56)	392 (54)	212 (53)	
ABI < 0.9	155 (24)	165 (20)	143 (15)	101 (14)	18 (5)	0.0001
Roche adjusted creatinine (mean ± SD)	2.56 ± 0.56	1.90 ± 0.32	1.56 ± 0.23	1.32 ± 0.20	1.14 ± 0.20	0.0001
Urine Protein/24 h (g; median [IQR])	0.57 (0.14 to 2.14)	0.26 (0.08 to 1.22)	0.13 (0.07 to 0.60)	0.10 (0.06 to 0.36)	0.10 (0.06 to 0.22)	0.0001
Lipoproteins						
total cholesterol (mg/dl; mean ± SD)	183.3 ± 51.6	182.5 ± 46.3	183.3 ± 42.1	183.2 ± 41.2	183.5 ± 39.2	0.7674
LDL cholesterol (mg/dl; mean ± SD)	99.9 ± 38.6	100.4 ± 35.6	103.3 ± 34.8	104.5 ± 33.2	107.2 ± 32.6	0.0001
HDL cholesterol (mg/dl; mean ± SD)	46.7 ± 15.5	47.4 ± 15.8	48.2 ± 14.8	48.8 ± 16.0	50.2 ± 16.4	0.0003
triglycerides (mg/dl; mean ± SD)	167.8 ± 126.8	162.3 ± 123.0	150.8 ± 99.0	148.3 ± 127.4	128.6 ± 81.5	0.0001
Hemoglobin (g/dl; mean ± SD)	11.8 ± 1.7	12.3 ± 1.7	12.8 ± 1.7	13.2 ± 1.6	13.4 ± 1.6	0.0001
Serum calcium (mg/dl; mean ± SD)	9.1 ± 0.6	9.2 ± 0.5	9.2 ± 0.5	9.2 ± 0.5	9.2 ± 0.4	0.0002
Total iPTH (pg/ml median [IQR])	104.5 (64.0 to 172.2)	63.9 (41.0 to 100.2)	47.8 (32.0 to 74.0)	40.9 (29.6 to 59.1)	36.0 (27.3 to 50.3)	0.0001
Serum phosphorus (mg/dl; mean ± SD)	4.1 ± 0.8	3.8 ± 0.6	3.6 ± 0.6	3.5 ± 0.6	3.4 ± 0.5	0.0001
Blood glucose (mg/dl median [IQR])	96.5 (85.0 to 124.0)	98.0 (87.0 to 131.0)	100.0 (88.0 to 127.0)	95.0 (85.0 to 119.0)	94.0 (84.0 to 110.0)	0.0003
Glycosylated hemoglobin (%; mean ± SD)	6.7 ± 1.5	6.8 ± 1.6	6.7 ± 1.5	6.5 ± 1.4	6.3 ± 1.7	0.0001
Serum uric acid (mg/dl; mean ± SD)	8.2 ± 2.0	7.9 ± 1.9	7.3 ± 1.8	6.8 ± 1.6	6.1 ± 1.7	0.0001

ABI, ankle-brachial index; ACEI, angiotensin-converting enzyme inhibitor; ARB, angiotensin receptor blocker; BMI, body mass index; DBP, diastolic BP; eGFR, estimated GFR; iPTH, intact parathyroid hormone; IQR, interquartile range; MAP, mean arterial pressure; MI, myocardial infarction; PAD, peripheral arterial disease; SB, systolic BP.  
<sup>a</sup>Includes Asian/Pacific Islanders and Native American individuals.

**Table 5. Select anticipated and actual recruitment targets: Race/ethnic target distribution in CRIC Study**

Race thnic Group	Anticipated (%)	Actual (%)
Non-Hispanic white	47.50	45.35
Non-Hispanic black	47.50	45.71
Other <sup>a</sup>	5.00	8.94

<sup>a</sup> For the purposes of recruitment goal, other group includes Hispanics, Asian/Pacific Islanders, and Native Americans.

**Table 6. Select anticipated and actual recruitment targets: Age- and diabetes-status distribution in CRIC Study**

Age Stratum (yr)	Anticipated Recruitment (%)		Actual Recruitment Cohort (%)	
	No Diabetes	Diabetes	No Diabetes	Diabetes
21 to 44 yr	12.50	12.50	9.55	3.99
45 to 64 yr	25.00	25.00	29.49	28.32
65 to 74 yr	12.50	12.50	14.31	14.34