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Impact of 'Black Race' Coefficient in eGFR on Our Community and Medical Education

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Short Title: Impact of 'Black Race' Coefficient in eGFR

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Abstract

Introduction: The use of race in estimation of glomerular filtration rate (eGFR) started a critical national conversation on numerous areas of medicine touched by racism; with a call for removal of race from calculation of eGFR. We scrutinized use of 'Black race' coefficient in MDRD eGFR calculation and consequence of its use on our local community in SW Michigan.

Methods: A cross-sectional analysis of de-identified electronic health record (EHR) data from routine outpatient primary care visits, from 1/1/2019 to 12/31/2019 included variables such as age, race, gender, serum creatinine levels and calculated eGFRs (if any), using Chi-square tests for association and Wald-approximation 95% confidence interval. During the data collection period in 2019, both hospital systems and the outpatient clinic site were all using MDRD.

Results: eGFR and associated CKD stage were calculated for 131,863 patients. Chi-square tests found significant differences in rates of CKD stages 3,4 and 5 between 'Black' and 'not Black'. And, the 95% confidence interval for the proportion of Black patients who would advance to the next stage of CKD upon ignoring 'Black race' (using Wald-approximated Confidence Interval for binomial proportion) is between 41.1% and 43.0%.

Discussion: The eGFR calculations which place Black patients in lower CKD stages initially may deprive them of important treatment and referral early in their disease course. Removal of the Black race coefficient allows for referral to a nephrologist, Medicare coverage, and the potential need for transplant and/or dialysis.

Conclusion: Our analysis demonstrates the impact removal of 'black race' coefficient from MDRD eGFR calculation could have on our community.

Introduction

The use of race in the calculation of estimated glomerular filtration rate (eGFR) has received national attention in recent years[1,2].

We know that eGFR is the most widely available and accepted measurement for kidney function . An individual's glomerular filtration rate is the sum of the filtration of all of the functional kidney units as plasma is filtered across the glomerular capillaries [3,4]

The direct measurement of kidney function presents logistical barriers. For this reason, clinicians and researchers have long sought calculations which accurately estimate true, or measured, GFR. Serum creatinine is produced endogenously by the body and its measurement is now a low-cost and ubiquitous indicator for kidney function[5,6] . It is used because creatinine clearance is only ~5-10% above that of inulin, an exogenous substance which is a gold standard for accurately measuring GFR [5,7,8]. The value of creatinine must be modified by an equation to estimate GFR, complicated by the variability of creatinine production, intake, and excretion, which has resulted in the inclusion of race, weight, sex, and age in calculation for a given individual.

The Modification of Diet in Renal Disease (MDRD) and, later, the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equations were developed in this way and are considered to be the best measures of eGFR by organizations such as the National Kidney Foundation (NKF) and the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) [9]. Within the distribution of the United States, Non-Hispanic Black people have the highest rate of chronic kidney disease – at 16%. In the past, defense of the use of race in MDRD has cited the fact Black populations have a higher rate of chronic kidney disease as justification [10].

Alternatives to the MDRD, CKD-EPI, and even use of serum creatinine (SCr) have been proposed. Cystatin C could be an alternate marker for eGFR and may be impacted by factors including gender, smoking status, height and weight, muscle mass, age, and CRP values, but perhaps to a lesser extent than creatinine [11–13]. Cystatin C may also be a better predictor of all-cause mortality in patients [14,15]. An amendment of the original, there exists a CKD-EPI-Cystatin C equation (2012) which only includes a correction for females and does not use a correction for race. The practical use of cystatin C (eGFRcys) or combined creatinine/cystatin C (eGFRcr-cys) may be limited due to laboratory diagnostic feasibility and longer turnaround time [16,17]. Though, an update, the 2021 CKD-EPI creatine equation refit without race (eGFRcr) and confirmatory assessment using eGFRcr-cys was recommended by NFK and the American Society of Nephrology (ASN) Task Force after reassessing inclusion of race [18]. Supplemental Table S1 gives a snapshot of equations used for eGFR.

Staging of Chronic Kidney Disease and Implications for Treatment

Chronic Kidney Disease (CKD) is defined as damage to kidney morphology or function for at least 3 months and decreased kidney function as defined by eGFR as noted in Supplemental Table S1 [19–21]. CKD stages are defined using the Kidney Disease Improving Global Outcomes (KDIGO) clinical practice guidelines [22] and staging influences healthcare outcomes by placing patients in different treatment categories for medication management, timing of referral to a nephrologist for specialty care, and being considered for kidney transplant (Table 1).

Epidemiology of Race and Kidney Disease

To examine the impact of changing eGFR equations, we must first understand two things: (1) the populations self-identifying as White, Black, mixed race, or other and (2) the burden of kidney disease in these groups. The current epidemiology of race and kidney disease in the U.S. and in SW Michigan (Kalamazoo County) is detailed in Table 2. Justification of using Black race in determining kidney function in the MDRD equation is inconclusive and more research to assess the impact of removing race in eGFR is needed [6], especially since race biases could be associated with decisions like potential kidney transplant eligibility[2].

In this exploratory study, on the broader context of race within medicine and the history eGFR calculations; we investigated how the use of Black race in eGFR affects our local community in Southwest Michigan. Our hypothesis explored if the rates of CKD stages are different between patients self-identifying as 'Black' or non-black race. And, if the omission of Black race coefficient (*1.212) in the MDRD equation would impact CKD stages in patients self-identifying as 'Black' race only. Especially since, during the data collection period in 2019, the local hospital systems and the outpatient clinic site were all using MDRD equation.

Methods

We conducted a retrospective cross-sectional analysis to determine the burden of chronic kidney disease via eGFR and its variations between racial groups in Southwest Michigan. Nonidentifiable EHR data was collected from 1/1/2019 to 12/31/2019 as part of routine outpatient primary care visits at two local healthcare systems and a local outpatient clinic of an academic center. During the data collection period in 2019, both hospital systems and the outpatient clinic site were all using MDRD. Variables of interest included age, race, gender, serum creatinine levels and calculated eGFRs (if any), zip code, ICD-10 code (International Classification of Diseases, Tenth Revision) clinical diagnosis associated with the lab order, and visit type from which the order was placed, and this information was provided by data brokers at each institution. For eGFR calculation, each location used the MDRD equation for each racial group and we then utilized KDIGO guidelines for CKD staging (Table 1).

Further analysis of eGFR calculation omitting the 'Black race' coefficient was determined for all subjects who self-identified as 'Black' in EHR. Prevalence of CKD and geographic distribution were assessed utilizing zip code. For patients with multiple serum creatinine measures within the study period, the highest value was taken into consideration in our results.

Our primary objective was to investigate if the rates of CKD stages are different between patients self-identifying as 'Black' or non-black race with and without the use of the Black race coefficient (*1.212) in the MDRD equation.

Questions we asked were:

Question 1: Is the rate of CKD Stage 3 or higher using MDRD equation different between Black and non-Black patients?

Question 2: Is the rate of Stage 4 or higher CKD different between Black and non-Black patients?

Question 3: Is the rate of Stage 5 CKD different between Black and non-Black patients?

Our secondary objective was to investigate any differences in demographic or associated condition characteristics amongst the Black patients who would advance a stage in CKD with those who would not advance.

Inclusion Criteria included:

- age greater than or equal to 18 years
- accessing primary care services at outpatient clinics noted above
- serum creatinine testing from 1/1/2019 to 12/31/2019.

This study underwent review and was approved by local IRB (IRB#:WMed-2020-0661).

Statistical Methods

Data analysis was done utilizing statistical analysis software, SAS® V9.4 (2013)**.** eGFR was calculated from SCr, sex, race, and age according to the MDRD equation as noted in Supplemental Table S1. eGFR was categorized into CKD stages noted in Table 1.

Patients' ages were categorized into the following groups: 18-19; 20-29; 30-39; 40-49; 50-59; 60-69; 70+.

The primary objective was met with three chi-square tests for association. The overall type-1 error rate was controlled at a level of 5% using a Bonferroni-adjusted significance threshold (α) of 0.016.

A Wald-approximation 95% confidence interval was used to estimate the binomial proportion of Black patients whose CKD stage as determined by MDRD equation would advance if 'Black race' coefficient (*1.212) was omitted.

Results

EGFR and associated CKD stage were calculated for all 131,863 patients. Characteristics of our study population is as noted in Table 3a, including CKD stages, demographic variables, and associated conditions. CKD stages by race for our study population is as noted in Table 3b.

The primary objective was met with three chi-square tests answering above three different questions regarding use of MDRD equation in determining burden of CKD stages as detailed below. Our data provided an affirmative answer to all three questions as noted in Table 4.

For Question 1, we found significant association between 'Black' and 'not Black' for CKD Stage 3 or higher with prevalence being 30% lower amongst Black (P-value < 0.0001.)

For Question 2, we found significant association between 'Black' and 'not Black' for CKD Stage 4 or higher with prevalence being 69% higher amongst Black patients (P-value < 0.0001.).

For Question 3, we found significant association between the variable indicating 'Black' and 'not Black' for CKD Stage 5, with prevalence being more than 3 times higher amongst Black patients (P-value < 0.0001).

We determined that omission Black race coefficient (*1.212) in the MDRD equation would not impact any other race except subjects identifying themselves as Black race only. We found that no data would change for the non-Black patients, but the calculated eGFR of Black patients would reduce by 17.5%. The changes in CKD staging, as it would affect our study population self- identifying as only 'Black,' are noted in Table 5a.

In our data, the 95% confidence interval for the proportion of Black patients who would advance to the next stage of CKD upon ignoring 'Black race' coefficient (using Wald-approximated Confidence Interval for binomial proportion) is between 41.1% and 43.0%.

Since no patients moved from Stage 4 into Stage 5, we can say with certainty that the third chi-square test (Table 4) would not change and while the significance of the first two tests would not change, the results do change substantially. These changes are summarized in Table 5b.

For the first test of association between race and CKD Stage 3 or higher, the difference in disease prevalence would reverse. Using MDRD equation with the 'Black race' coefficient, the rate of CKD Stage 3 or higher was 30% lower among Black patients than non-Black patients, but omitting the 'Black race' coefficient, the rate of CKD Stage 3+ would be 45% higher among Black patients than non-Black patients.

For the second test of association between race and CKD Stage 4 or higher, the difference in disease prevalence would become more pronounced since the rate of CKD Stage 4+ was 69% higher among Black patients than non-Black patients even using the 'Black race' coefficient. Omitting the 'Black race' coefficient, the rate of CKD Stage 4+ would increase to be 154% higher among Black patients than non-Black patients. Similarly for the third test of association for and CKD Stage 5, omitting the 'Black race' coefficient, would increase to be 323% higher among Black patients than non-Black patients.

There were no significant differences noted in demographic or associated condition characteristics amongst the Black patients who would advance a stage in CKD (n=4229) with those who would not advance (n=5921) (Supplemental Table S2).

Discussion

Based on our data, 34% of Black patients in southwest Michigan with CKD would advance to Stage 3 from Stage 2 if the MDRD equation was used without 'Black race' coefficient. There are significant differences in management and treatment of CKD that occur when a patient enters Stage 3 CKD, including standard of referral to establish care with a nephrologist [22].

Our data also finds that, with removal of the Black race coefficient, 9% of Black patients would advance to Stage 4 (from Stage 3) CKD. This is important because patients with a history of progressive CKD and an eGFR of ≤ 20 mL/min/1.73m^2 (within Stage 4) qualify for addition to the renal transplant list [22].

There is a disconnect between the proportions of Black vs non-Black patients with end stage renal disease (ESRD), as 66.6% more Black patients fall into Stage 5 when compared to non-Black patients across the U.S. population according to the United States Renal Data System (USRD) data from years 2015-2018 (https://adr.usrds.org/2020/chronic-kidney-disease/1-ckd-in-the-general-population; accessed October 15, 2021). It may not be immediately apparent why there is an isolated, higher proportion of Black patients in ESRD, given the lower rates for this patient group across the first four CKD stages when compared to non-Black patients. In fact, there are mortality benefits to early referral to a nephrologist in the first stages of CKD [23] The eGFR calculations which place Black patients in lower CKD stages initially may deprive them of important treatment and referral early in their disease course. As early escalation in care slows or prevents the progression to ESRD, it appears that Black patients are systematically excluded from this benefit, and it seems reasonable to infer this may contribute to the increased proportion of Black patients who progress to Stage 5 CKD.

Many laboratories report CKD Stages 1 and 2 as ">60," and only enumerate eGFR values, and therefore discrete staging, below 60 mL/min/1.73m^2 – beginning with CKD Stage 3. Our data finds that of Black patients in our community currently in Stage 2, whose data may currently be reported as ">60," and of no concern, would be moved into Stage 3 by removal of the race coefficient from eGFR calculation. This has significant implications for provider awareness and disease management.

Removal of the Black race coefficient allows for referral to a nephrologist, Medicare coverage, and potentially need for transplant and/or dialysis. CKD is also an independent risk factor for other comorbid conditions, such as cardiovascular disease. Earlier CKD diagnosis could allow providers to manage risk factors preemptively, like

tightening diabetic, hypertensive, and lipid control, and potentially affect Medicare coverage for individuals who need transplant or dialysis, alleviating financial burden of ESRD[22,24] . While it is considered on a case-by-case basis within Stage 5, expediting transplant eligibility could help some patients financially.

Conclusions

Our analysis of eGFR calculation in our community of SW Michigan establishes that a significant number of Black patients would be advanced to CKD Stage 2 (from 1), and to Stage 3 (from 2) with the removal of the race coefficient. Given the call for better detection, earlier awareness, and more prompt referrals, removal of the race coefficient would clearly move us toward those goals in our own community.

Thoughts on Future Directions

In 2021, the American Society of Nephrology (ASN) and the National Kidney Foundation (NKF) published a recommendation on removal of race from eGFR and use of the CKD-EPI equation refit without race, which is now in use on their website [25].

Considering these updated recommendations along with the results of our work, there are several future directions for investigation, including:

- Analysis of long-term patient outcomes as the removal of 'Black race' coefficient is implemented
- Evaluation of the updated eGFR calculation on pediatric, elderly, and other population groups with comorbid conditions (chronic illness, immunosuppression, etc.)
- Follow-up on how and when this new recommendation and underlying reasoning are integrated into medical education and medical student literature (textbooks, didactic materials, question banks).

We expect robust research on these topics to continue and hope that medical students will remain unafraid to question the status quo and move medicine forward.

Statement of Ethics

Deidentified data was provided by data brokers from each institution in congruence with IRB protocol. Informed consent was not obtained as this study was granted exempt status with waiver of HIPAA authorization after review by Ethics Committee/ Institutional Review Board (IRB) at Western Michigan University Homer Stryker M.D. School of Medicine (IRB#: WMed-2020-0661) in accordance to OHRP 45CFR 46 regulations for the protection of human subjects in research and the research was conducted ethically in accordance with the World Medical Association Declaration of Helsinki.

Conflict of Interest Statement

The authors have no conflicts of interest to declare.

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Author Contributions

Concept, design, method, writing of complete manuscript, critical review for important intellectual content: Shibani Kanungo. Equal contribution of manuscript writing: Amy R. Lorber, Christine Schmitt, Kaitlyn VanRiper. Biostatistical analysis and manuscript writing: Joseph Billian.

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Data Availability Statement

All data generated or analyzed during this study are included in this article and its supplementary material files. Further enquiries can be directed to the corresponding author.

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Table 1. CKD stages and management

CKD Stage*	**GFR (mL/min/1.73m^2)**[26]	**General Management†**	**Additional Impacts**[27]
Stage 1	≥ 90	Manage medically and **address comorbid conditions**	**Impacts drug dosing** (e.g. Use of SGLT-2 inhibitors in Type 2 DM limited to eGFR ≥ 30) **Changes clinical interventions and screening** for related conditions (anemia, malnutrition, mineral and bone disorders) Affects the results specified by **Kidney Failure Risk Calculator**
Stage 2	60 - 89	**Track progression** and continue previous management	
Stage 3	30 - 59	**Address complications** and continue previous management	
Stage 4	15 - 29	**Nephrology consult indicated** (evaluation for renal replacement therapy and/or transplant) and continue previous management	
Stage 5 (ESRD[a])	< 15	**Begin renal replacement therapy and/or transplant**	

*Definitions of the Stages of Kidney disease according to the Center for Disease Control.
†Standard of management by stage according to the American Academy of Family Physicians.
[a]ESRD is End-Stage Renal Disease and is another term used for Stage 5 CKD.

Table 2. Demographics and Prevalence of CKD in U.S. and Michigan

Race	US population (%)[30]	Kalamazoo County, Michigan (%)[31]	Total prevalence of CKD in US (%)[32]	Total prevalence of CKD in Michigan[33] (%)	Total prevalence of ESRD in Michigan (%)[33]	Mortality Rate Stage 4-5 for >65yr old (%)[33]
White alone, not Hispanic or Latino	57.8	81.75	15.7	25	0	11
Hispanic or Latino	18.7	*	11.9	28	2	
Black or African American	12.1	10.89	16	36	2	8.5
Asian	5.9	2.08		26	1	
American Indian and Alaska Native	0.7	0.42		28	1	
Native Hawaiian and Other Pacific Islander	0.2	0.035				
Two or More Races	4.1	3.29				
Some other Race alone	0.5	1.52				

Source:
United States 2020 Census Data on racial demographics of the United States and Kalamazoo County, Michigan.
United States Renal Data System (USRDS) data on prevalence of CKD Stages stratified by race and mortality stratified by race and CKD stages., accessed in October 2021. USRDS collects data from the CMS, UNOS, and ESRD organizations to compile data on chronic kidney disease.
Total prevalence of CKD in Michigan 27% (as of 2019); 1% with ESRD.
*Data not specified in Census.

Table 3a. Study Population Characteristics

Characteristics		Frequency (Percent)
CKD Stage	1	29,117 (22.1%)
	2	76,391 (57.9%)
	3	24,533 (18.6%)
	4	1,413 (1.1%)
	5	409 (0.3%)
Gender	Female	75,908 (57.6%)
	Male	55,945 (42.4%)
	Other	*[not reported if #≤ 10]*
Age	18-19	1,479 (1.1%)
	20-29	9,572 (7.3%)
	30-39	13,656 (10.4%)
	40-49	18,368 (13.9%)
	50-59	25,361 (19.2%)
	60-69	31,242 (23.7%)
	70+	32,185 (24.4%)
Race	Black	10,220 (7.8%)
	Not Black	121,643 (92.3%)
Nephropathy	Yes	6,366 (4.8%)
	No	125,497 (95.2%)
Diabetes	Yes	17,069 (12.9%)
	No	114,794 (87.1%)
Hypertension	Yes	30,610 (23.2%)
	No	101,253 (76.8%)

Table 3b. **CKD stages by Race in study population**

Race	Study population (%)	CKD Stage 1 (%)	CKD Stage 2 (%)	CKD Stage 3 (%)	CKD Stage 4 (%)	CKD Stage 5 (%)
All	100%	22%	58%	19%	1.1%	0.31%
White Alone	86%	19%	60%	20%	1.1%	0.24%
Black or African American alone	7.8%	41%	45%	12%	1.3%	0.93%
American Indian and Alaska Native alone	0.42%	23%	57%	18%	1.3%	0.72%
Asian alone	1.4%	40%	52%	6.8%	0.44%	0.39%
Native Hawaiian and other Pacific Islander alone	0.09%	27%	55%	16%	0	1.8%
Some other race alone	2.8%	44%	47%	8.1%)	0.94%	0.52%
Two or more races	N/A	N/A	N/A	N/A	N/A	N/A

Table 4. Prevalence of CKD Stages with MDRD Equation

Prevalence of CKD Stages determined by MDRD Equation			
	Non-Black	**Black**	Chi Square
	Frequency (Percent)	Frequency (Percent)	**P-value**
Stages 3, 4 & 5	24,893 (20%)	1,463 (14%)	< 0.0001
Stages 4 & 5	1,593 (1.3%)	229 (2.2%)	< 0.0001
Stage 5	314 (0.26%)	112 (1.10%)	< 0.0001
Total Patients	121,643	10,220	

Table 5a. CKD Stage changes without MDRD 'Black race' Coefficient

CKD Stage (EGFR range)	Total Number of Black Patients, using MDRD Equation	Number (Percent) of Black Patients who would ADVANCE to next CKD stage using MDRD equation without 'Black race' coefficient
Stage 1 (≥90)	4147	2602 (63%)
Stage 2 (60 – 89)	4610	1571 (34%)
Stage 3 (30 – 59)	1234	109 (9%)
Stage 4 (15 – 29)	117	0
Stage 5 (<15)	112	N/A
TOTAL	10220	4282 (42%)

Table 5b. Changes in CKD Stage 3+, 4+, 5+

		Using **MDRD equation** with 'Black race' coefficient		Using **MDRD equation** without 'Black race' coefficient	
	Prevalence, non-Black	Prevalence, Black	Difference between Black & non-Black (% of non-Black)	Prevalence, Black	Difference between Black & non-Black (% of non-Black)
CKD Stage 3+	20%	14%	-30%	29%	+45%
CKD Stage 4+	1.3%	2.2%	+69%	3.3%	+154%
CKD Stage 5	0.26%	1.10%	+323%	1.10%	+323%