An Endorsement of the Removal of Race From GFR Estimation Equations: A Position Statement From the National Kidney Foundation Kidney Disease Outcomes Quality Initiative

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As this article reflects the official position of the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (NKF-KDOQI) and because it was reviewed and approved by NKF-KDOQI, it was not peer reviewed by AJKD. This article was prepared by the KDOQI chairs and led by Dr Holly Kramer. It was reviewed and approved by the NKF Scientific Advisory Board.

In July 2020, the National Kidney Foundation (NKF) and the American Society of Nephrology (ASN) formed a joint task force to reassess the use of race in the diagnosis of kidney diseases. After multiple sessions with stakeholders, such as clinical laboratory scientists, epidemiologists, and ancestry experts, including open forums for patients and their families and clinicians, the NKF-ASN joint task force released a report in 2021 that made recommendations for an equitable approach for glomerular filtration rate (GFR) estimation and outlined existing gaps in knowledge and research needs.[1] The NKF Kidney Disease Outcomes Quality Initiative (KDOQI) strongly supports the joint task force recommendations for the immediate implementation of the 2021 Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) creatinine-based GFR estimating equation without a race variable; increased use of cystatin C where possible; and the continued examination, identification, and validation of filtration biomarkers than can improve the accuracy of equations for estimated GFR (eGFR). KDOQI also agrees with the task force's call for more research to identify and implement a consistent and equitable approach to GFR estimation. Removal of the race modifier to estimate GFR is only one small step for equity in kidney disease diagnosis and treatment, and further research and implementation of interventions to reduce chronic kidney disease (CKD) disparities by race and ethnicity are needed, as highlighted by a recent NKF research roundtable.[2] This Position Statement discusses the recommendations of the NKF-ASN task force and how it advances the KDOQI goals of improving CKD diagnosis and treatment and eliminating health disparities in kidney disease.

Most chronic diseases produce symptoms that incite patients to seek diagnosis and care, but the identification of CKD, which is often asymptomatic, requires laboratory testing. CKD continues to be underdiagnosed and undertreated for several reasons such as gaps in laboratory testing and low clinician recognition and action regarding abnormal test results.[2] In the United States, approximately 37 million adults have CKD, but most remain unaware of their condition.[3,4] Gaps in CKD testing and diagnosis are not uniform across populations, and the delivery of preventive care to avoid CKD or delay its progression and to reduce cardiovascular risk differs by income, insurance status, education level, and race and ethnicity.[5-8] Individuals from underrepresented communities are disproportionately affected by kidney failure,[4] and earlier detection and treatment of kidney disease could delay progression to kidney failure, reduce cardiovascular risk and health disparities, improve survival, and lower health care costs. Due to the asymptomatic nature of kidney disease, however, earlier and wider diagnosis and treatment requires better awareness with public health initiatives, input from multiple health care sectors, and equitable approaches for all individuals at risk for kidney diseases.[3,9]

With its clinical practice guidelines and commentaries, KDOQI aims to improve the diagnosis and treatment of kidney disease. Over the past 2 decades, KDOQI guidelines have changed the practices of health care professionals and improved outcomes for people with kidney disease. To address gaps in CKD identification, KDOQI released the very first guideline for CKD diagnosis and classification 20 years ago.[10] This guideline recommended that clinicians utilize an eGFR equation that incorporates serum creatinine and one or more demographic variables (eg, age, sex, race), such as the Modification of Diet in Renal Disease (MDRD) Study equation (Table 1).[11] The MDRD Study equation was developed using data from 1,431 White and 197 Black study participants.[11] Because Black race was associated with higher levels of serum creatinine for a given measured GFR, as was younger age and male sex, the MDRD Study equation included a coefficient for Black race, along with coefficients for age and sex. This coefficient for Black race meant that if all other variables (age, sex, serum creatinine) were the same, the expected mean measured GFR would be 21% higher for Black versus Non-Black adults.

More accurate eGFR equations were later introduced such as the 2009 CKD-EPI creatinine equation ($eGFR_{cr}$ equation)[12] and the 2012 CKD-EPI creatinine–cystatin C and cystatin C equations ($eGFR_{cr\text{-}cys}$ and $eGFR_{cys}$ equations)[13] (Table 1). The 2009 CKD-EPI $eGFR_{cr}$ and 2012

Table 1. Change in Reported eGFR With Black Race by Equation

Description	Formula	Change in Reported eGFR With Black Race
4-Variable MDRD Study equation[11]	$eGFR = 175 \times Scr^{-1.154} \times age^{-0.203} \times 1.212$ [if Black] $\times 0.742$ [if female]	21% higher
2009 CKD-EPI creatinine equation[12]	$eGFR = 141 \times \min(Scr/\kappa, 1)^{\alpha} \times \max(Scr/\kappa, 1)^{-1.209} \times 0.993^{age} \times 1.018$ [if female] $\times 1.159$ [if Black], where κ is 0.7 if female and 0.9 if male, α is -0.329 if female and -0.411 if male, min indicates the minimum of Scr/κ or 1, and max indicates the maximum of Scr/κ or 1	16% higher
2012 CKD-EPI creatinine–cystatin C equation[13]	$eGFR = 135 \times \min(Scr/\kappa, 1)^{\alpha} \times \max(Scr/\kappa, 1)^{-0.601} \times \min(Scys/0.8, 1)^{-0.375} \times \max(Scys/0.8)^{-0.711} \times 0.9952^{age} \times 0.969$ [if female] $\times 1.08$ [if Black], where $\kappa = 0.7$ if female and 0.9 if male, $\alpha = -0.248$ if female and -0.207 if male, min indicates the minimum of Scr/κ or 1, and max indicates the maximum of Scr/κ or 1	8% higher
2021 CKD-EPI creatinine equation refit without race variable[15]	$eGFR = 142 \times \min(Scr/\kappa, 1)^{\alpha} \times \max(Scr/\kappa, 1)^{-1.20} \times 0.9938^{age} \times 1.012$ [if female], where $\kappa = 0.7$ if female and 0.9 if male, $\alpha = -0.241$ if female and -0.302 if male, min indicates the minimum of Scr/κ or 1, and max indicates the maximum of Scr/κ or 1	No change
2021 CKD-EPI creatinine–cystatin C equation refit without race variable[15]	$eGFR = 135 \times \min(Scr/\kappa, 1)^{\alpha} \times \max(Scr/\kappa, 1)^{-0.544} \times \min(Scys/0.8,1)^{-0.323} \times \max(Scys/0.8)^{-0.778} \times 0.9961^{age} \times 0.0963$ [if female], where $\kappa = 0.7$ if female and 0.9 if male, $\alpha = -0.219$ if female and -0.144 if male, min indicates the minimum of Scr/κ or 1, and max indicates the maximum of Scr/κ or 1	No change

The 2012 CKD-EPI $eGFR_{cys}$ equation did not include a race coefficient and accordingly was not refit in 2021. Abbreviations: CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; eGFR, estimated glomerular filtration rate; MDRD, Modification of Diet in Renal Disease; Scr, serum creatinine; Scys, serum cystatin C.

CKD-EPI $eGFR_{cr-cys}$ equations are not only more accurate than the MDRD Study equation, but unlike their predecessor they are also valid in the eGFR range of 60-90 mL/min/1.73 m^2, which can help inform care particularly relevant to earlier diagnosis of CKD.[3,9] The 2009 CKD-EPI $eGFR_{cr}$ and 2012 CKD-EPI $eGFR_{cr-cys}$ equations led to a 16% and 8% higher estimated GFR, respectively, in Black individuals compared to non-Black individuals for the same age, sex, and serum creatinine level (Table 1).[12,13]

Higher estimated GFR with use of the race modifier has been proposed to account for delays in referrals to a nephrologist or wait-listing for kidney transplantation in Black individuals.[14] Simply removing the race coefficient from existing eGFR equations could lead to over- or underestimation of GFR and errors in CKD diagnosis and staging as well as inappropriate medication use and/or dosing. However, the 2021 CKD-EPI $eGFR_{cr}$ equation refit without a race modifier[15] will enable the assessment of kidney disease using a consistent eGFR equation for all US racial and ethnic groups, and KDOQI enthusiastically supports the recommendation of the NKF-ASN task force to implement this equation.

Implementation of the 2021 CKD-EPI $eGFR_{cr}$ equation could potentially remove barriers for some Black patients for the timely diagnosis of CKD, referral to nephrologist, and access to the kidney transplant waitlist.[14] However, the overall impact on racial disparities in kidney disease care remains unknown; moreover, racial disparities in kidney failure and treatment existed before the implementation of eGFR equations. Thus, the nephrology community must recognize that the implementation of the 2021 CKD-EPI $eGFR_{cr}$ equation may not substantially impact racial disparities in kidney disease diagnosis and treatment. As recommended by the NKF-ASN task force, more research is urgently needed to identify and implement actionable interventions to reduce racial, ethnic, and socioeconomic disparities in kidney disease diagnosis and treatment.

The performance of the 2021 CKD-EPI eGFR equations in Black and Non-Black adults versus measured GFR as reported by Inker et al[15] is shown in Table 2. The 2021 CKD-EPI $eGFR_{cr}$ equation without the race variable is not as accurate as the 2009 CKD-EPI $eGFR_{cr}$ equation that includes a race variable, but importantly the newer equation shows less systematic difference between Black and non-Black race groups and maintains sufficient accuracy to implement for use in most clinical decisions. However, estimation of GFR continues to rely on serum creatinine. Serum creatinine levels reflect GFR and tubular secretion but also non-GFR factors because creatinine is a by-product of creatine catabolism found in muscle.[16] Cystatin C is filtered but not secreted by the tubules, and serum levels are less strongly influenced by demographic factors.[17] Clinical factors such as obesity, inflammation, and diseases and medications that affect cell turnover have been found to be associated with cystatin C levels, but eGFR equations that utilize cystatin C alone show less bias by race groups compared to equations that utilize creatinine alone.[13,18] Although serum creatinine and cystatin C alone have limitations as GFR biomarkers, use of creatinine in combination with cystatin C to estimate GFR (as in the 2021 CKD-EPI $eGFR_{cr-cys}$ equation) is beneficial because it leads to the most accurate estimates and also reduces the difference in bias in GFR estimates between Black and non-Black individuals (Table 2).[15]

Table 2. Performance of the CKD-EPI GFR Estimating Equations Lacking Race Variable by Black Versus Non-Black Race

	Black Adults			Non-Black Adults		
	Bias	P_{30}	Correct Classification	Bias	P_{30}	Correct Classification
2021 CKD-EPI $eGFR_{cr}$	3.6	87%	62%	−3.9	86%	67%
2012 CKD-EPI $eGFR_{cys}$	−0.1	85%	63%	0.7	89%	66%
2021 CKD-EPI $eGFR_{cr\text{-}cys}$	0.1	91%	68%	−2.9	91%	70%

Data adapted from Inker et al.[18] Abbreviations and definitions: CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; eGFR, estimated glomerular filtration rate; $eGFR_{cr}$, eGFR based on creatinine; $eGFR_{cys}$, eGFR based on cystatin C; $eGFR_{cr\text{-}cys}$, eGFR based on creatinine and cystatin C; bias, difference between measured and estimated GFR; P_{30}, percentage of eGFR that are < 30 mL/min/1.73 m^2 different from measured GFR; correct classification, eGFR in same category (<30, 30-44, 45-59, 60-89, and >90 mL/min/1.73 m^2) as measured GFR.

KDOQI supports the NKF-ASN task force recommendations to increase use of the 2021 CKD-EPI $eGFR_{cr\text{-}cys}$ equation to confirm estimated GFR when more accurate estimates of GFR are needed such as with drug initiation and/or dosing changes. This recommendation is congruent with 2012 KDIGO guideline,[19] which suggested using additional markers such as cystatin C or clearance measurements to confirm GFR when eGFR based on creatinine alone is suspected to be less accurate, such as very low or high muscle mass or when more accurate GFR estimates are needed for clinical decision making (Box 1).

Clearance measurements to confirm eGFR include the urinary clearance of iothalamate and plasma clearance of iohexol, which are available in the United States and correlate highly with inulin clearance.[20] However, clearance measurements of iothalamate and iohexol are more expensive and time-consuming than measuring cystatin C. The recommendation for increased use of cystatin C to estimate GFR was further supported by the KDOQI commentary[21] on the 2012 KDIGO CKD guideline. The commentary discussed concerns about incorporating cystatin C–based GFR estimates into clinical practice because most clinical laboratories do not measure cystatin C,[17] precluding its timely use.

Cystatin C can be measured on a wide range of instruments, and fully automated tests can be completed with a turbidimeter or nephelometer. Only a minority of clinical laboratories that perform creatinine assays also measure cystatin C, and not all participate in the international assay harmonization efforts, despite availability of a certified reference material.[17] These potential barriers for cystatin C measurement can be avoided via utilization of commercially available assays that participate in international harmonization efforts.[17]

Another limitation of cystatin C is cost. The 2021 Medicare laboratory fee schedule is $18.52 for cystatin C (CPT 82610) versus $5.12 for creatinine (CPT 82565) testing,[22] and widespread use for patients without CKD could in aggregate lead to a large increase in health care expenditures.[17] Without a Medicare national coverage determination, there is also concern for cystatin C costs being placed on patients. Higher utilization of cystatin C could potentially lower costs and incentivize more laboratories to perform cystatin C assays.

KDOQI agrees with the NKF-ASN task force that national efforts are needed to make cystatin C or other clearance markers routinely and more readily available to clinicians. KDOQI also supports research that addresses new approaches for more accurate and less biased estimates of GFR without the inclusion of race.

As stated by the NKF-ASN task force, research funding and support is needed to develop and implement other interventions to eliminate race and ethnic disparities in CKD diagnosis and treatment. KDOQI has consistently advocated for continued research and development of more accurate and less biased equations and for the examination of the performance of eGFR equations in the general population across the full range of age, sex, race, ethnicity, protein intake, and comorbid conditions. An urgent investment in science is needed for newer approaches that generate accurate, unbiased, and precise GFR assessment.

Box 1. When to Use Cystatin C

- When confirmation of CKD is required in adults with eGFR based on serum creatinine of 45-59 mL/min/1.73 m^2 alone without markers of kidney damage
- When more accurate estimation of GFR is required for drug dosing (due to narrow therapeutic or toxic range) or other clinical decision making
- When confirmation or exclusion of CKD is needed in patients with very low or high muscle mass; examples include individuals with spinal cord injury and paraplegia or quadriplegia or severe neuromuscular disease, advanced liver or heart disease (low muscle mass), and body builders and professional athletes (high muscle mass)
- When estimation of GFR is required in patients taking medications that inhibit tubular creatinine secretion with eGFR < 60 mL/min/1.73 m^2

Abbreviations: CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; GFR, glomerular filtration rate.

Table 3. Possible Consequences for CKD Diagnosis and Nephrology Referral With Implementation of the Race-free CKD-EPI Equations in the US Adult Population

	CKD-EPI Equation		
	2021 $eGFR_{cr}$	2012 $eGFR_{cys}$	2021 $eGFR_{cr\text{-}cys}$
Change in Black Adult Population			
Change in number of adults with eGFR < 60 mL/min/1.73 m^2	+0.64 million (+31%)	+0.09 million (+4%)	+0.09 million (+4%)
Increase in number of false CKD diagnoses	Moderate	Minimal	Minimal
Change in nephrology referral	Minimal	+0.12 million (+26%)	Minimal
Drug initiation to slow CKD progression	Increase	No change	No change
Inappropriate drug discontinuation and underdosing	Increase or no change	No change	No change
Change in Non-Black Adult Population			
Change in number of adults with eGFR < 60 mL/min/1.73 m^2	−3.14 million (−23%)	+4.29 million (+29%)	−1.36 million (−9%)
Change in nephrology referral	−0.29 million (−26%)	+1.46 million (+133%)	+0.61 million (+55%)
Drug initiation to slow CKD progression	Decrease	No change	No change
Inappropriate drug continuation and overdosing	Increase	No change	No change

Data adapted from Delgado et al.[1] Abbreviations: CKD, chronic kidney disease; CKD-EPI, Chronic Kidney Disease Epidemiology Collaboration; $eGFR_{cr}$, estimated glomerular filtration rate based on creatinine; $eGFR_{cr\text{-}cys}$, eGFR based on creatinine and cystatin C; $eGFR_{cys}$, eGFR rate based on cystatin C.

The 2021 CKD-EPI $eGFR_{cr\text{-}cys}$ equation shows only 68% and 70% agreement with measured GFR for CKD staging in Black and non-Black adults, respectively (Table 2).[15] Inaccuracies in GFR estimation could lead to errors in clinical decision making such as inappropriate initiation or discontinuation of metformin and sodium/glucose cotransporter 2 inhibitors; incorrect initiation of or under- or overdosing of chemotherapy; poorly timed initiation of other life-saving drugs; and late referral for kidney transplant evaluation and listing, nephrologist care, and dialysis access placement (Table 3). Inaccuracies could also curtail enrollment of Black adults in clinical research studies.[23]

The NKF-ASN task force also addressed body surface area (BSA) indexing of GFR. Estimated GFR is indexed for 1.73 m^2 BSA, which may lead to errors when an individual's BSA differs substantially from 1.73. KDOQI supports the NKF-ASN task force recommendation that eGFR reporting by a laboratory be accompanied by a statement that "use of nonindexed eGFR values (mL/min) should be considered for drug dosing decisions"[1] because nonindexed GFR correlates better with the clearance of medications that are excreted by the kidneys. The use of nonindexed eGFR may be clinically relevant if the BSA is ≤1.65 m^2 or ≥1.9 m^2.[24] For persons with obesity whose BSA is at least 1.9 m^2, Titan et al[24] showed that eGFR indexed for 1.73 m^2 BSA may underestimate measured GFR by 10 mL/min; the underestimation is 20 mL/min for persons with BSA ≥2.0 m^2 with a mean measured GFR of 68 ± 32 mL/min/1.73 m^2. For persons with a BSA ≤1.65 m^2, eGFR indexed for 1.73 m^2 BSA may overestimate the nonindexed eGFR by at least 10 mL/min. To remove BSA indexing, the eGFR is multiplied by the individual's BSA calculated with height and weight[25] and divided by 1.73 m^2; that is, nonindexed eGFR in mL/min = eGFR in mL/min/1.73 m^2 × patient BSA in m^2/1.73 m^2.

In summary, the NKF-ASN task force recommends the immediate implementation of the 2021 CKD-EPI $eGFR_{cr}$ equation refit without the race modifier because it will provide greater equity in the assessment of kidney disease. KDOQI supports this recommendation and encourages all US laboratories and clinics to implement the 2021 CKD-EPI $eGFR_{cr}$ equation, and incorporate referent-standardized cystatin C into metabolic panels.[26] When more accurate GFR estimates are needed, KDOQI agrees that the 2012 CKD-EPI $eGFR_{cys}$ equation, which has lower bias,[13] or the 2021 CKD-EPI $eGFR_{cr\text{-}cys}$ equation[15] should be considered.

Changing how we estimate GFR will not eliminate health disparities in kidney disease, and the nephrology community needs to further identify and implement strategies to mitigate factors that contribute to differences in kidney disease diagnosis and treatment as well as kidney disease outcomes by race, ethnicity, income, education, and insurance status. While continued research, evaluation, and validation of filtration biomarkers and eGFR equations are needed to ensure continued advancement of the diagnosis and treatment of kidney diseases for all, we also must actively and vigilantly address how racism, health policies, genetics, access to care, and social and environmental factors influence kidney disease disparities.

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