Kidney Medicine

A Canadian Commentary on the NKF-ASN Task Force Recommendations on Reassessing the Inclusion of Race in Diagnosing Kidney Disease

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In 2021, a committee was commissioned by the Canadian Society of Nephrology to comment on the 2021 National Kidney Foundation–American Society of Nephrology Task Force recommendations on the use of race in glomerular filtration rate estimating equations. The committee met on numerous occasions and agreed on several recommendations. However, the committee did not achieve unanimity, with a minority group disagreeing with the scope of the commentary. As a result, this report presents the viewpoint of the majority members. We endorsed many of the recommendations from the National Kidney Foundation–American Society of Nephrology Task Force, most importantly that race should be removed from the estimated glomerular filtration rate creatinine-based equation. We recommend an immediate implementation of the new Chronic Kidney Disease Epidemiology Collaboration equation (2021), which does not discriminate among any group while maintaining precision. Additionally, we recommend that Canadian laboratories and provincial kidney organizations advocate for increased testing and access to cystatin C because the combination of cystatin C and creatinine in revised equations leads to more precise estimates. Finally, we recommend that future research studies evaluating the implementation of the new equations and changes to screening, diagnosis, and management across provincial health programs be prioritized in Canada.

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INTRODUCTION

Inclusion of race in clinical algorithms in medicine has led to significant disparities in care.[1,2] Additionally, the use of race-adjusted algorithms has continued to perpetuate racism and race-based medicine across various subspecialties in medicine.[2-4] Race-adjusted clinical algorithms are based on flawed assumptions that differences in race account for biological differences which has often assumed biological inferiority in Black and other historically marginalized individuals. Another inherent flaw with race-adjusted algorithms is how can it be reasonably applied to individuals with different ethnicities or mixed racial backgrounds? Additionally, health equity research has demonstrated that race correction in clinical algorithms normalizes racial stigmatization and biases, leading to negative outcomes for patients.[4,5] As result of this practice, there is often a diversion of resources from historically marginalized individuals, who are often in the most need of support from our health care system.[4] Accordingly, there is an urgent need for the removal of race correction in algorithms to address health care disparities that emanate from racist ideologies and practices.

Since its development in 2009, the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation was adopted worldwide to estimate kidney function with an adjustment for Black race. The inclusion of Black race in the CKD-EPI equation results in higher estimates of glomerular filtration rate (GFR) in Black people with the same level of serum creatinine, potentially leading to an underdiagnosis of chronic kidney disease (CKD). In North America, Black people are more likely to develop CKD and to progress more rapidly on onset and are less likely to be referred for specialist nephrology care.[6] Additionally, estimated glomerular filtration rate (eGFR) is essential in determining eligibility for certain medications and elective procedures. Depending on the eGFR, there can be delays in the timing of dialysis modality education or referral for transplant assessment. This further deprives Black patients access to kidney transplantation or home dialysis.[7-9]

Given these prevalent disparities in kidney disease care and the mounting research demonstrating higher morbidity and mortality resulting from this practice,[10-12] the National Kidney Foundation (NKF) and American Society of Nephrology (ASN) commissioned a task force in 2020 to review the use of race in eGFR equations.[13] Emerging data led the NKF-ASN Task Force to endorse 3 key recommendations (summarized below) regarding the use of race as a factor in eGFR estimating equations.[14] This has also prompted a reassessment of the use of race for eGFR equations in the Canadian landscape,[6] and as such, the Canadian Society of Nephrology requested a specially devised committee to review the task force recommendations with the aim of providing explicit guidance to Canadians.

In this commentary, we discuss the recommendations, providing guidance about practice implications and implementation within the Canadian health care system. The authors recognize and strongly endorse the elimination of race correction for GFR estimates. Newer equations using cystatin C alone or in combination with creatinine

provide better estimates of GFR and should be adopted across Canada to reduce downstream effects related to disparities in kidney disease care.[15]

We are cognizant that revised estimates of GFR without the race coefficient may lead to reclassification of CKD stages for some patients; however, this must be counterbalanced with the reduction in disparities in care at the population level. Additionally, this will serve as a reminder that eGFR is an estimate and that no one equation is perfect. Therefore, individuals should not rely on a single value to guide treatment decisions related to CKD care and diagnosis. We should instead focus on measuring albuminuria and repeating eGFR measurements coupled with using clinical judgment when considering progression risk. Our primary aim with this commentary is to provide a framework for changing practice and to bring to attention disparities in kidney care built on reliance of race-based equations and a unidimensional focus on eGFR as the only measure of kidney health in Canada. Additionally, the delivery of kidney care across Canada is overseen by various provincial renal organizations under the auspices of the ministry of health at the provincial level. Although we can only comment on a Canadian-specific context, we believe that models of care around the globe such as in Canada may identify similar challenges and opportunities to implementation that we have outlined in this commentary. As such, this commentary should be relevant to all practitioners, health care administrators, laboratories, provincial kidney organizations and, most importantly, patients within the Canadian health care system and beyond.

NKF-ASN TASK FORCE RECOMMENDATION 1

For US adults (>85% of whom have normal kidney function), we recommend immediate implementation of the CKD-EPI creatinine equation refit without the race variable in all laboratories in the United States because it does not include race in the calculation and reporting, included diversity in its development, is immediately available to all laboratories in the United States, and has acceptable performance characteristics and potential consequences that do not disproportionately affect any one group of individuals.

Authors' Recommendation 1

"The authors strongly endorse the task force recommendation that we immediately cease the use of the race coefficient and implement the new refit CKD-EPI creatinine equation throughout Canada to ensure equitable kidney disease care."

Commentary

We agree that refitting the CKD-EPI creatinine equation without the race variable is an important first step in achieving equitable care for Black patients in Canada. The original CKD-EPI equations were developed with a race variable, and in some Canadian jurisdictions, non-Black and Black eGFRs are reported, and physicians may decide to use a multiplier manually to re-estimate GFRs for Black patients. Leaving the original equations as is and simply advising physicians to no longer use the multiplier is unlikely to change clinical practice. As a result, we feel that replacement of the equations is the best path forward to widespread implementation of removing race from eGFR in Canadian practice. We recognize that the updated equation without race results in a small bias (Fig 1) for both Black and non-Black individuals but feel that the magnitude of the bias is acceptable and similar to the change seen when labs moved from the Modification of Diet in Renal Disease Study equation to the CKD-EPI equation.[15,16] For instance, a negative number for the bias overestimates measured GFR, whereas a positive number underestimates measured GFR. The combined eGFR creatinine-cystatin C (eGFRcr-cys) equation has a median bias of 0.1 mL/min/1.73 m^2 in Black individuals and a bias of −2.9 mL/min/1.73 m^2 in non-Black individuals with classification accuracy rates of 68% and 70%, respectively.[15] This is marginally better than cystatin C alone (eGFRcys), which yields a median bias of −0.1 mL/min/1.73 m^2 in Black participants and a bias of 0.7 mL/min/1.73 m^2 in non-Black participants with classification accuracy rates of 63% and 66%, respectively. Classification accuracy refers to the degree of agreement between measured GFR and eGFR in determining different stages of CKD. Therefore, laboratories should consider implementation of cystatin C for routine investigations to improve care decisions for patients with established kidney disease along with other high-risk groups including individuals with diabetes, hypertension, and cardiovascular disease.

Implications Within Canadian Health Care

We believe that there are important implications that must be considered in adopting new equations in Canadian practice that may have an impact on CKD stage classification, drug eligibility, insurance coverage, and clinical trial eligibility.

First, we recognize that there may be reclassification of CKD staging among some individuals with the new GFR equations in Canada. Although large population data that examine the reclassification of CKD stage using the eGFRcys-cr and eGFRcys are limited, these equations provide less differential bias and would have minimal effect on restaging and overall care that patients receive. Recent data from the United States examining the impact that the new CKD-EPI 2021 race-free equation using creatinine demonstrated that about 16.7% of Black individuals had a reclassification of CKD from stage 1 (>90 mL/min/1.73 m^2) down to stage 2 (60-89 mL/min/1.73 m^2),[17] whereas 35.2% of non-Black individuals had the greatest reclassification, from stage 3A CKD (45-59 mL/min/1.73 m^2) up to stage 2 CKD (60-89 mL/min/1.73 m^2). Additionally, for both Black and non-Black individuals, reclassification of CKD to earlier stages when GFR is <15 mL/min/1.73 m^2 occurred in 5.7%-7.8% of

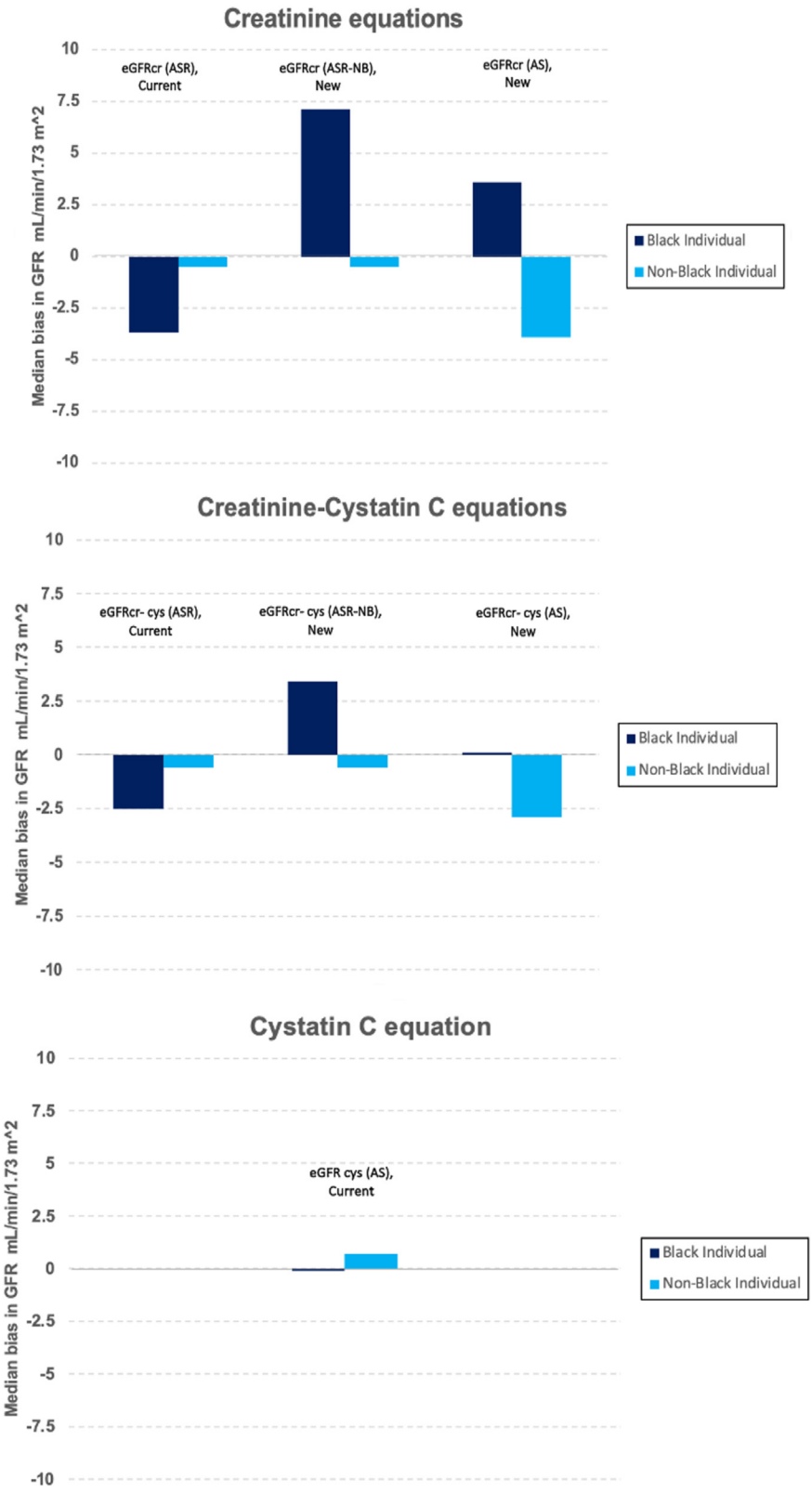

Figure 1. Median differences between estimated GFR and measured GFR across the different equations. A positive number indicates an underestimation of measured GFR and a negative number indicates an overestimation of measured GFR. Adapted with modification from Inker et al.[15]

patients.[17] The findings highlight that much of the reclassification of CKD would occur at much earlier stages of CKD. This is unlikely to result in significant delay in access to care for patients, given that most Canadian renal provincial organizations do not recommend referral for CKD stage 3A in isolation, and clinical decision making for an eGFR of 58 or 62 mL/min/1.73 m^2, in the absence of albuminuria, should not change.

Additionally, in terms of demographics, the population in the United States has many similarities that are reflective of the diversity in Canada, but a specific examination of the effect that the new equations will have on the Canadian population will be needed. We recommend future research within the Canadian population to examine the impact of CKD reclassification using the revised race-free equation along with other cystatin C-based equations to ensure that any downstream effects leading to disparities in care can be addressed. This also serves as an opportune time to reassess the reliance on hard cutoff thresholds to determine treatment pathways for patients. CKD stages are in fact arbitrary thresholds, and practitioners should consider whether a few mL/min difference in eGFR has greater significance than development or changes in albuminuria, worsening risk of progression, or suboptimally controlled diabetes or hypertension.

For example, in the province of Ontario, Canada's most populous province, (population of 15.5 million people), the KidneyWise Clinical Toolkit is used to provide guidance on the identification and management of CKD in primary care.[18] It also provides general practitioners some guidance on when to refer patients to nephrology for kidney care. Referral guidelines depend on a combination of albuminuria and/or eGFR levels.[18] Similar toolkits exist in various provinces across the country that allow for similar referral practices regardless of jurisdiction. Therefore, even with CKD reclassification that may occur with newer equations, there is unlikely to be meaningful change that is disruptive in access to care across Canada. However, if there is a reliance on a single eGFR value, then there may be potential for underdiagnosis or overdiagnosis of CKD among individuals, with implications on the access to care. As such, clinical algorithms that use single eGFR cutoffs for critical drug dosing decisions may require closer scrutiny and consider serial measurements of eGFR or the use of creatinine and cystatin C to estimate kidney function. This may increase costs for more cystatin C or more frequent testing of serum creatinine levels but will facilitate more equitable care, reduce discrimination, and assure optimal use of kidney care resources. The use of serial measurements may also provide a more reliable baseline for a given individual and combined with albuminuria and cystatin C, may lead to better prognostication.

In addition, there must be continuous efforts on educating both patients and care providers about the limitations of accuracy in GFR, both with estimation and the measured approach using gold standard yet impractical methods such as iothalamate or inulin clearance. These radionucleotide-based measurements are considered the gold standard for measuring kidney function but are also susceptible to analytical variability and can be influenced by technique. Greater emphasis on a multidimensional approach to CKD care that includes measurement of albuminuria and a focus on etiology and risk of progression could ameliorate health system challenges resulting from excessive reliance on eGFR-based staging.

Finally, Black patients and other historically marginalized groups are often underrepresented in clinical trials, which can exacerbate disparities in care.[19] The impact that the new equations will have on clinical trial enrollment is quite important to consider, particularly if it may exacerbate care disparities. Recent analysis of the inclusion and outcomes of patients enrolled in the Canagliflozin and Renal Events in Diabetes with Established Nephropathy Clinical Evaluation trial was evaluated after calculating eGFR using the 2009 CKD-EPI creatinine equation with and without a race-specific coefficient or the 2021 CKD-EPI creatinine equation.[20] In reviewing the randomized population, if the CKD-EPI 2021 equation had been used, proportional enrollment of Black patients would have increased because 8% of non-Black participants compared with 4% of Black randomized participants would have been excluded. This underscores the importance and need for continuing to monitor the effects that the newer equations will have on trial enrollment and interpretation of results.

NKF-ASN TASK FORCE RECOMMENDATION 2

We recommend national efforts to facilitate increased, routine, and timely use of cystatin C, especially to confirm estimated GFR in adults who are at risk for or have chronic kidney disease, as the combination of filtration markers (creatinine and cystatin C) is more accurate and would support better clinical decisions than either marker alone. If ongoing evidence supports acceptable performance, the CKD-EPI eGFR-cystatin C ($eGFR_{cys}$) and eGFR creatinine-cystatin C ($eGFR_{cr\text{-}cys\_R}$) refit without the race variables should be adopted to provide another first-line test, in addition to confirmatory testing.

Authors' Recommendation 2

"We recommend that Canadian health authorities and laboratory providers work to increase access to Cystatin C as an additional endogenous marker to estimate GFR, as it provides more accurate estimates of GFR when used in conjunction with serum creatinine."

Commentary

Despite refitting the CKD-EPI equation without race, the use of creatinine presents numerous limitations including changes in muscle mass (amputations, body builders, muscle wasting diseases), dietary restrictions, drugs that affect proximal tubular secretion of creatinine (eg, cimetidine, cobicistat, dolutegravir, fenofibrate, ritonavir,

trimethoprim), laboratory-to-laboratory variation, assay variation (Jaffe vs enzymatic), and assay-dependent interferences (Jaffe: glucose, ketones, bilirubin, cephalosporins; enzymatic method: flucytosine) along with extrarenal elimination by intestinal bacteria.

Although cystatin is not readily available in laboratories, emerging evidence supports its use to provide estimates of similar accuracy with fewer non-GFR determinants when compared to creatinine.[16] Additionally, when cystatin C is combined with creatinine (eGFRcr-cys) it provides better estimates than cystatin C alone.[15,16] Although cystatin C alone (eGFRcys) demonstrates the lowest differential bias between Black and non-Black individuals (Fig 1), it is less accurate in estimating GFR compared to the refitted CKD-EPI equation.[15] Currently, cystatin C is not available as a first-line test for GFR estimations and should be used in combination with creatinine where available. This is particularly important as there are some limitations with cystatin C that must be considered beyond its higher cost and limited availability. Cystatin C is influenced by age, diabetes, inflammation, glucocorticoid therapy, and obesity.[8-10] Additionally, observational data show that thyroid dysfunction can affect cystatin C levels, with lower cystatin C levels in those with hypothyroidism.[21-23]

In adopting these revised equations, laboratories must consider some important factors with implementation. When reporting eGFR with the eGFRcr(AS), eGFRcr-cys, or eGFRcys equations, laboratories should use an upper linearity limit of 90 mL/min/1.73 m^2; values above 90 should be reported as >90 mL/min/1.73 m^2. Lower linearity should be set to 5 mL/min/1.73 m^2, whereas values below 5 should be reported as <5 mL/min/1.73 m^2. Although these equations were validated for use in adults ages 18 and older, a recent equation was developed and validated using Chronic Kidney Disease in Children Study for individuals under age 25.[24] As a result, laboratories should also consider adopting the Chronic Kidney Disease in Children Study under 25 GFR estimating equations for the pediatric population in Canada. Finally, the equations are also only applicable to patients with kidney function in steady state and may be misleading in cases of acute kidney disease.

Implications Within Canadian Health Care

We recognize that cost along with the lack of standardized approach to both ordering and measuring cystatin C may be a significant barrier for widespread adoption across Canadian laboratories. Although there is a certified reference material (ERM-DA471/IFCC),[25] laboratories will require close collaboration to develop consensus on methods to avoid intervariability in results. A lack of standardized approach in methods may have an impact on serial monitoring, particularly when patient samples are analyzed at different laboratory locations. In specific kidney disease populations, such as those requiring corticosteroids for glomerulonephritis, considerable variability in cystatin C values may occur that may affect reliable interpretation. Future research may be required to assess the utility of cystatin C in patients with glomerulonephritis. Therefore, relevant care providers should be aware, foster collaboration, and aim to standardize measures by adopting combined the eGFRcr-cys equation or the refitted CKD-EPI equation without race rather than cystatin C alone (eGFRcys).

Similar to the United States, the community laboratories in Canada are highly consolidated and provide the majority of testing services to Canadian patients with CKD. Given budget constraints, universal adoption of cystatin C testing for kidney function as part of the eGFRcr-cys equation is not part of routine testing across Canada at this time. However, efforts should be made to integrate cystatin C into clinical laboratory practice starting with the most appropriate use cases—these may include its role as a "rule out" CKD test in patients with an eGFRcr of 45-59 mL/min, in patients with extremes of muscle mass, and in those where more precision around the eGFR measurement is desired for accurate drug dosing or for treatment eligibility (eg, chemo- or immunotherapy for malignancy).

As it relates to drug dosing, the use of an indexed eGFR with body surface area (mL/min/1.73 m^2) presents challenges when estimating kidney clearance of medications, particularly at extremes of weight.[26] In using an indexed eGFR, there may be an increased risk of medication underdosing in patients with a higher body surface area and overdosing in those with a lower body surface area.[26] Pooled data from 9 studies that included a diverse group of individuals around the globe had an indexed eGFR that was significantly lower for a nonindexed measured GFR for all the new equations.[27] Therefore, the use of indexed eGFR may potentiate disparities in populations that may be at an increased risk of obesity, resulting in suboptimal medication dosing and treatment.

It is therefore essential that research with a diverse population continues to examine the safety thresholds of these agents when using cystatin C. The authors encourage provincial health funding bodies to support the integration of cystatin C in the community laboratory framework starting with these settings.

NKF-ASN TASK FORCE RECOMMENDATION 3

Research on GFR estimation with new endogenous filtration markers and on interventions to eliminate race and ethnic disparities should be encouraged and funded. An investment in science is needed for newer approaches that generate accurate, unbiased, and precise GFR measurement and estimation without the inclusion of race, and that promote health equity and do not generate disparate care.

Authors' Recommendation 3

We partially agree with the recommendation. We believe that the priority must focus on designing robust research

studies that evaluate the implementation of the new equations and impact on screening, diagnosis, and management in Canada. These research studies should also include in their design a deliberate effort to consider intersectionality and social determinants of health among Black, Indigenous, and other marginalized populations.

Commentary

Although the task force highlights the need for future work in addressing care disparities in the section "Gaps in Knowledge and Future Science," we believe that identification of new filtration markers should not be the immediate priority. Rather, more robust research studies to examine the impact of race on incidence, outcomes, and kidney care should be prioritized.[4] Self-identified race is not consistently collected at health care interactions in Canada, and a more systematic approach to collection of self-identified race and ethnicity data is needed. Advocacy across provincial health care systems should focus on collection of self-identified data at the time of registration for health care. This will ensure collection of race and ethnicity for all Canadians and allow for analyses of access to care, testing, and treatments. We believe that recognizing race as a social construct rather than a biological one can assist in realigning research priorities. Additionally, we also recognize that a better understanding of intersectionality and its impact of health outcomes for historically marginalized groups is desperately needed. The search for a new, perfect filtration marker should not supersede a deeper understanding of the inequalities in the Canadian Health system.

Implications Within Canadian Health Care

Canada has a rich immigration history, and Black people in Canada come from diverse communities. Among these are Canadians of African Nova Scotian, African, Caribbean, Afro-Indigenous, and multiracial descent. Many Black Canadians are multigenerational, along with recent immigrants. Black people represent about 3.5% of the Canadian population with about 15.6% of the population identifying as a visible minority.[28] Other high-risk groups for development and progression of CKD in Canada include Indigenous people as well as immigrants from Asia. Studies evaluating current and future filtration markers need to be widely inclusive of these groups to develop the best future estimating equations for all Canadians. In adopting newer and revised equations, we must also assess performance in predicting kidney function across broad aspects of the population, including extremes of age, hospitalized individuals, and those with other significant medical comorbid conditions, to ensure generalizability as a screening test. We recognize that innovative research must be at the forefront after implementation so as to facilitate an ongoing audit of the performance of new equations and to identify any negative balancing measures that lead to unintended consequences in patient care.

IMPLEMENTATION AND FUTURE DIRECTIONS

There will be significant challenges to implementation that include cost and other competing priorities, particularly in a health care system that is beleaguered by resource constraints. However, we are steadfast in our recommendations that changes are needed. In overcoming challenges to implementation of new equations in Canada, we believe broad engagement with stakeholders including providers, patients, health care organizations, professional associations, laboratories, and policy makers at the provincial and federal levels will be required. We recognize that without strong commitment of stakeholders, broad adoption of new eGFR equations will be delayed and unsuccessful.

Further strategies to mitigate delayed adoption would include providing equipment and financial support to laboratories that allow them to perform cystatin C testing. Laboratories are encouraged to collaborate with each other and test manufacturers to achieve standardization of results. Additionally, unequal access to cystatin C testing could present additional challenges that may perpetuate inequities in care, particularly in remote areas where centers may not offer the test. In collaborating with regional health authorities, laboratories can provide guidance about implementation barriers in remote areas such that the test is accessible to many across the country.

In the interim, an initial step that laboratories across Canada can undertake is the adoption of the new CKD-EPI refit equation without the race variable. At present, eGFR reporting is not standardized across Canadian laboratories, and this would serve as means to standardize reporting as an initial step in adopting the new, race-free CKD-EPI equation. If we are to implement broader adoption of cystatin C-based equations, we must continue to evaluate its impact on the care that patients receive. We must also bring patients, community leaders, and partners to the table in providing future guidance about approaches that go beyond equation modifications that help reduce disparities in kidney care. This change in equation is long overdue, but we must ensure that we restore patient trust with active engagement. We also need to conduct research of Black populations and other historically marginalized groups to see how the new equations perform in Canada. This research must be done in consultation with patients and community partners and in collaboration with health equity and implementation science experts.

CONCLUSIONS

Changes are urgently needed to adopt the new eGFR equation refit without race for clinical screening, diagnosis, and management. Reporting of eGFR should be updated by laboratories across Canada. This approach is fundamental to addressing the long-standing disparities in the delivery of kidney care in Canada. Practitioners should not rely on a single eGFR to make treatment decisions but serial measurements and a combination of other

investigations including albuminuria, kidney failure risk equations, and clinical assessment. Removing race and updating clinical testing for kidney function is an important first step toward achieving equitable kidney health for all Canadians, but it cannot stop here. These authors, and the Canadian Society of Nephrology, urge health care organizations and policy makers to support initiatives that target biomedical, clinical, and population health research to improve kidney health for all.

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While it is true that a minority of members voiced concerns about the rigor and structure of our committee's final manuscript, it is important to underscore that the majority of our group recognized the significance of our work and perspective. The committee's mandate was never intended to replicate the efforts of the NKF-ASN Task Force recommendations, but rather to offer high-level commentary on how these recommendations could be effectively applied within the Canadian context. Ultimately, 2 members formed the minority dissenting opinion, and 2 other members abstained from authorship of this report.

The dissenting opinion, calling for a more in-depth approach, raised valid points; however, it was the collective view of the majority that this high-level commentary aligns with the original mandate outlined by the Canadian Society of Nephrology. We acknowledge the need for future endeavors that delve deeper into implementation science and assess the impact on Canadian nephrology. As a follow-up to this commentary, we remain committed to pursuing further work that will enhance the field and benefit Black patients within the nephrology community in Canada. Once again, we extend our sincere appreciation to all members for their dedication and contributions to this committee.

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