Health Care Equity and Justice Scorecard To Increase Diversity in Clinical Trial Recruitment and Retention

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Black or African American and Hispanic or Latinx groups make up 13.4% and 18.4%, respectively, of the United States (US) population,1 yet they have the highest prevalence of CKD, up to 16% and 14%, respectively, compared with 13% for non-Latinx White people.2 Black or African American people also have a two- to four-fold greater incidence of kidney failure and a 3-fold greater risk of progressing to kidney failure, typically occurring at an earlier age and up to 5 years sooner than their White counterparts and accounting for 35% of adults with kidney failure.2 A key aspect to advancing health equity and ensuring access to high quality health care for all is by achieving increased diversity in clinical trials. The US Food and Drug Administration (FDA) 2020 Drug Trial Snapshot reports that only 11% Latinx and <10% Black or Asian, compared with 75% non-Latinx White participants were among the 32,000 participants enrolled in clinical trials.3,4 To ensure adequate diversity in clinical trial enrollment, trial sponsors should aim to mirror the demographic distribution of patients with the condition, and not simply reflect the US population. For example, clinical trials that target American population.1 Indeed, the FDA acknowledged the need to increase diversity in clinical trials so that individuals most likely to use the potential therapeutics are fully represented, and endorses strategies to overcome barriers to clinical trial enrollment for underrepresented populations.

The Health Care Justice Committee (HCJC) of the American Society of Nephrology (ASN) was created in recognition of the disparities and health inequities that exist in CKD and the understanding that policies which support kidney health should be rooted in the principle of justice to identify opportunities to promote justice in our health care system and society by influencing the social and structural determinants of health, particularly in populations at-risk for and overburdened with CKD. Therefore, HCJC is charged with encouraging diversity, inclusiveness, and equity to enhance the nephrology profession and the lives of people with CKD through health care justice, research, and education. The HCJC Committee created three workgroups comprising individuals with personal experiences with CKD, health services researchers, health care professionals, and members of the ASN Diversity, Equity, and Inclusion Committee, the ASN Policy and Advocacy Committee, and the Kidney Health Initiative Board, who liaise and synergize our efforts. HCJC workgroups assess Education to develop an antiracism core competency educational curriculum; Scholarship & Advocacy to provide guidance for community-academic partnerships; and Clinical Care & Innovation to develop a health care equity and justice scorecard for the pharmaceutical and medical product industry that aligns with the FDA on setting guidelines to promote increased diversity in clinical trials.

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| Clinical trial and other research recruitment | Increase diversity in kidney disease-related clinical trials | • Premarket reporting of diversity action plan: Describe how researchers will meet targeted diverse enrollment, include outreach and enrollment strategies, study-site selection, clinical trial inclusion/exclusion practice, diversity of research staff, and diversity and culturally responsive training for research personnel.  
  • Explicit diversity plan: Include prevalence of the disease or condition in the United States for which the research is being developed and disaggregate by demographic subgroup (age, sex, gender, race, ethnicity).  
  • Target enrollment: The research involved should be similarly disaggregated by age, sex, gender, group, race, and ethnicity. Targeted enrollment may include:  
    a. Increased proportions of clinical trial sites in safety-net clinics and hospitals  
    b. Increased proportions of clinical trial sites in urban neighborhoods (by census tracts or postal codes) with high proportion of racial and ethnic minorities and those in rural areas  
    c. Reimbursement for travel, lost wages, and other social needs that serve as barriers to clinical trial participation (childcare, transportation, extended recruitment hours). |
| Patient and community engagement | Who | • Patient partners: Individuals and organizations with the lived experience or who are representative of population of interest (e.g., patients, caregivers, community-based organizations).  
  • Stakeholder partners: Individuals and organizations with professional experience (e.g., clinicians, policy makers, industry, hospitals and health systems, payers).  
  Create advisory boards of stakeholders that include pharma/industry representatives, patients, and other stakeholder groups. |
| Planning the study | | • Describe how patient and stakeholder partners will participate in study planning and design (e.g., partner on research question, provide feedback on outcomes, define characteristics of study participants, design the study). |
| Conducting the study | | • Describe how patient and stakeholder partners are involved in drafting the institutional review board study consent form to make sure it is at the appropriate health literacy level (e.g., simplified, at 3rd grade level) and there is clarity about how a patient will benefit from participation.  
  • Describe how patient and stakeholder partners will participate in the study conduct (e.g., preparation of study materials and protocols, recruitment of study participants, evaluation of patient and stakeholder engagement, serving as patient representative on a data safety monitoring board). |
| Disseminating the study results | | • Describe how patient and stakeholder partners will be involved in plans to disseminate study findings and to ensure that findings are communicated in understandable, usable ways (e.g., partner with organization for dissemination, plan dissemination efforts, participate in dissemination efforts, identify opportunities to present or share information). Describe whether results seen by specific subgroups represent a biologic or social difference. |
| Principles | | • Trust, honesty, transparency: Major study decisions made inclusively and information should be shared with all partners. Ensure accountability by reporting results back to patients and describing next steps from information learned. All (partners and researchers) should be committed to honest communication.  
  • Reciprocal relationships: Roles and decision-making authority should be defined collaboratively.  
  • Co-learning: The goal is not to turn patient and community partners into researchers, but to help them understand the research process. Research team will then learn about patient-centeredness and patient and stakeholder engagement.  
  • Partnerships: Ensure that time and contribution from partners are valued and demonstrated with financial compensation and with thoughtful request for time commitment. |
| Clinical trial leadership and diversity | Create advisory board of stakeholders | • The advisory board: This should include patient and nonprofit groups (e.g., Kidney Health Initiative, National Kidney Foundation), and can promote diversity in leadership positions, among internal research teams, and among patient and partner stakeholders. |
HEALTH CARE EQUITY AND JUSTICE SCORECARD

To open a path to increased diversity in clinical trial recruitment, the Clinical Care & Innovation Workgroup developed a health care equity and justice scorecard as a tool that the pharmaceutical and medical product industry may utilize. Table 1 shows the scorecard domains and activities to enhance inclusion in stakeholder committees and inclusion in guidelines; it also describes targeted areas to accomplish the themes. The scorecard recommendations follow in the footsteps of the Association of Black Cardiologists which advocates for diversity in clinical trials aimed at reducing racial bias in clinical decision making and supports their responses on the Diversity and Equitable Participation in Clinical Trials Act. The scorecard also supports the initiatives of the International Society of Nephrology to increase the number, size, and quality of clinical trial investigation, and advances the National Kidney Foundation kidney-related research priority theme on expansion in inclusivity in clinical trials.

Clinical Trial and Other Research Recruitment
A culturally responsive clinical trial diversity action plan should target pertinent age, gender, and racial and ethnic subgroups with the highest disease prevalence for the proposed therapeutic as early as the study design phase, and not after study enrollment has begun. Clinical trial recruitment sites should be in geographic locations where the targeted cohorts are likely to be identified (e.g., safety-net clinics, urban neighborhoods) and should aim to reduce critical barriers to clinical trial participation (e.g., childcare, transportation, extended recruitment hours).

Patient and Community Engagement
At each aspect of the study, diverse participant engagement may be enhanced with inclusion of patient partners (e.g., PatientLikeMe), community engagement, and stakeholder partners including kidney patient advocacy groups (e.g., American Association of Kidney Patients, American Kidney Fund, Renal Support Network). The inclusion of stakeholder partners at the onset of study design can incorporate patient activation measures, contribute to methodologies, and provide feedback on outcomes that are relevant to the targeted population and on informed consent forms that enable full comprehension by all participants, even for individuals with low health literacy. An important facet not previously incorporated in clinical trial design is dissemination and interpretations of study results germane to the communities and study participants most affected by the disease. Although recommendations related to specific patient-related outcome measures are beyond the scope of the current scorecard, we anticipate that future scorecard iterations may include novel, validated measures for targeted populations and communities. It is crucially important to include principles of transparency, reciprocal relationships, co-learning, and partnerships throughout the study design, and to maintain diversity in postmarketing surveillance studies.

Clinical Trial Leadership and Diversity
An important aspect to strengthening clinical trial diversity is establishing and maintaining diversity in all study roles. For example, an advisory board of stakeholders with patient and nonprofit representation (e.g., FDA, Kidney Health Initiative, National Kidney Foundation) may promote diversity in leadership positions, in internal research teams, and among patient and partner stakeholders.

CONCLUSION
The health care equity and justice scorecard is a novel strategy that is intended to increase diversity in kidney disease clinical trial populations. As the first iteration, it encourages the kidney research community to take action toward increasing clinical trial diversity and retention at several levels. Subsequent iterations will provide steps toward scorecard dissemination, widespread adoption, and appropriate and inclusive metrics for scoring, and offer suggestions on incentives for sponsor participation and ways to incorporate sponsor accountability to maintain clinical trial diversity.

DISCLOSURES
L. Cervantes reports research funding from Retrophin/Travere; reports advisory or leadership role with Retrophin/Travere; and reports interests or relationships with the National Kidney Foundation. S. Nicholas reports consultancy with AstraZeneca, Bayer, Boehringer Ingelheim, George Clinical, Goldfinch, Janssen Pharmaceutical, Novo Nordisk, Terasaki Institute for Biomedical Innovation, and Travere; reports research funding from Bayer, Goldfinch, Terasaki Institute for Biomedical Innovation, and Travere; reports honoraria from AstraZeneca, Bayer, Boehringer Ingelheim/Lilly, George Clinical, Janssen Pharmaceutical, and Novo Nordisk; reports patents or royalties with University of California, Los Angeles; has advisory or leadership roles with the National Kidney Foundation of Southern California and Nevada Medical Advisory Board Executive Committee (volunteer President), Women of Nephrology (volunteer President-Elect), AstraZeneca, Bayer, Boehringer Ingelheim/Lilly, George Clinical, Janssen Pharmaceutical, and Novo Nordisk; and is on the speakers bureau for AstraZeneca, Bayer, Boehringer Ingelheim, and Janssen Pharmaceutical.

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AUTHOR CONTRIBUTIONS

L. Cervantes and S. Nicholas conceptualized the study and reviewed and edited the manuscript; and S. Nicholas wrote the original draft.

REFERENCES