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September 25, 2020

The Honorable Richard Neal
Chairman
Committee on Ways and Means
United States House of Representatives
Washington, DC 20515

Dear Chairman Neal,

I am pleased to respond to your letter pertaining to race and health inequality dated September 3, 2020. On behalf of The American College of Cardiology (ACC), I thank you for engaging us in this important discussion and look forward to continuing our collaborative efforts together. We commend you for your proactive commitment to these issues and are pleased to address the specific questions you presented.

I acknowledge that these questions, and our responses, are complex and nuanced. I and other leaders in the College request the opportunity to meet with you to discuss the below points in greater detail.

ACC envisions a world where innovation and knowledge optimize cardiovascular care and outcomes. As the professional home for the entire cardiovascular team, the mission of the College and its more than 54,000 members is to transform cardiovascular care and improve heart health. The ACC bestows credentials upon cardiovascular professionals who meet stringent qualifications and leads in the formation of health policy, standards, and guidelines. The College also provides professional medical education, disseminates cardiovascular research through its world-renowned JACC Journals, operates national registries to measure and improve care, and offers cardiovascular accreditation to hospitals and institutions.

ACC Actions to Address Issues of Health Inequality

The ACC is fully committed to addressing issues of race and health disparities that impact Black, Hispanic, Indigenous, and other communities of color. The ACC strives to educate its membership about these pervasive topics and is actively working to increase the diversity of the cardiovascular workforce. Specifically, the ACC's 2019-2023 Strategic Plan includes the following Diversity and Inclusion Goals:

1. To ensure that the diverse health needs of cardiovascular patients and populations are met by cardiovascular clinicians sensitive to and prepared to meet the unique needs of their gender, cultural, racial and ethnic background and other dimensions of diversity.
2. To ensure that cardiovascular medicine benefits from a diversity of backgrounds, experiences and perspectives in leadership, cardiovascular health care delivery, business, education and science.
3. To ensure that cardiovascular medicine attracts and provides rewarding career and leadership opportunities for the full range of talented individuals.

To achieve these goals, the ACC has taken the following actions:

Implicit Bias Training: The ACC is committed to training approximately 2,000 ACC leaders, as well as its staff, in implicit bias. To begin, the ACC has already trained our top leaders, including the Board of Trustees. Understanding the roles of "gatekeepers" in cardiology fellowships, the ACC also sponsored implicit bias training for 100 cardiovascular training program directors during the ACC Program Director Symposium in October 2019.

Stakeholders' Summit: In 2019, the ACC convened 30 nationally recognized Diversity and Inclusion experts across multi-sector organizations to inform the ACC on best practices in building a strong pipeline of Black cardiologists and developing strategies to address health disparities.

Internal and Structural Changes

- Recognizing that diversity in medicine is essential to quality patient care, the ACC in 2017 established a Task Force on Diversity and Inclusion charged with providing strategic recommendations regarding diversity and inclusion in cardiovascular medicine.
- In 2019, the ACC established the role of Chief Diversity Officer to lead and expand the College's diversity and inclusion initiatives.
- Earlier this year, the ACC launched the Health Equity Task Force, with the goal of identifying principles and recommending strategies to position the ACC to play a leading role in efforts to address racism and social justice and achieve health equity.
- The ACC has established an annual Distinguished Award for Leadership in Diversity and Inclusion, as well as an annual Chapter Award for Diversity and Inclusion.
- In 2019, a public policy priority survey was conducted of members of the ACC's Diversity and Inclusion Task Force. This provided valuable information to identify keys to build advocacy efforts to address the ACC's Diversity and Inclusion Goals.
- The ACC's #TheFaceOfCardiology social media campaign, coupled with regular Diversity and Inclusion Town Halls, "Listening Tours" and a dedicated communications campaign have served to educate cardiovascular clinicians and begin to change culture and perceptions.
- More than two-thirds of the ACC's 150 Committees, Sections and Chapters are undertaking diversity and inclusion activities.

Deep/Immediate Pipeline Programs: Data from the Accreditation Council for Graduate Medical Education (ACGME) from 2010 show that 4.3% of cardiology trainees were Black and 6.3% were Hispanic, compared to 5.7% and 9.1%, respectively, in internal medicine during that same period. Overall, less than 10% of medical students and less than 3% of medical school faculty are Black[1].

[1] https://www.acc.org//~/media/Non-Clinical/Files-PDFs-Excel-MS-Word-etc/About%20ACC/Diversity/2018/03/Diversity-Inclusion-Strategy-Summary.pdf

Addressing how to diversify the cardiac workforce involves improving the medical training pipeline from the very beginning. From middle school through cardiology fellowship training and beyond, the ACC is working to increase the number of cardiologists from under-represented groups in the field as well as those in medical leadership roles. Current programs include Young Scholars, Leadership Academy, and the Clinical Trials Research Program (see below) as well as partnering with the Posse Foundation and Young Physicians Initiative to introduce high school and college students to careers in cardiology. Additionally, the College is working to add formal mentoring and other programs, as well as targeted tools and resources at key stages, including middle school and high school, medical school, and residency.

Clinical Trials Research Program (CTR): The ACC recognizes the need to diversify the population of individuals conducting medical research and patient populations participating in clinical trials. Through specific actions, **the ACC will work to ensure diversity of thought, experience, and perspective of those involved in clinical trials, resulting in data more closely reflecting the demographics of actual cardiovascular patients.**

The ACC will hold a two-day virtual session in November 2020 titled "Clinical Trials Research: Upping Your Game for 2020 and 2021!" The course is designed to expose traditionally underrepresented groups to clinical trials research and allow them to network with current investigators.

The ACC has offered and is developing numerous educational modules for members specific to its Diversity and Inclusion goals. Many of these modules will be eligible for Continuing Medical Education (CME) credits.

- Healthcare Disparities and COVID-19: The Story Behind the Headlines
- The Burden of Battle: Understanding Impact of Emotional Trauma in Black Healthcare Professionals and Your Patients
- ACC Guide to Discussing Racism, Race and Ethnicity in Professional Settings
- Sexual and Other Harassment: What ACC Members Need to Know (in progress, CME module)
- Microaggressions Can Cause Macro Harm (in progress, CME module)
- Social Determinants of Health (in progress, CME module)
- Career Advancement of Women Cardiologists (in progress, CME module)

The Use of Clinical Guidelines to Improve Heart Health

In addition to these actions, the ACC is dedicated to using real world data from its national clinical registry programs to understand historical patterns of clinical treatment compared to evidence-based science. Research based on clinical registry data has contributed to the medical literature highlighting gaps and disparities in

quality of care and patient outcomes, including by race.[2][3][4][5][6] The College has been – and remains – fully committed to developing quality improvement initiatives to address such gaps or disparities. As one example, the ACC, in collaboration with the AHA and multiple other healthcare stakeholder organizations, spearheaded the national 'Door to Balloon' quality initiative, to address persistent delays in life-saving cardiac procedures in the setting of heart attacks. This national quality initiative was highly successful, leading to more rapid heart attack care across the U.S. Of note, with successful implementation of the quality of care strategies, **Black Americans had among the greatest improvements in timely heart attack care, with significant reduction in disparity.**[7][8][9]

Nonetheless, the College is fully aware that treatment gaps can be lessened or exacerbated when "real-world," or observational, data are used to inform risk stratification and treatment decisions. Biases can also be reflected in historical datasets, including those influenced by social, cultural, economic, and other variables. Thus, great vigilance is needed by all health care stakeholders, especially medical professional societies. Learning how this data can be turned into information within the context of medical decision making is crucial. **The ACC is committed to finding ways in which risk stratification tools and algorithms can serve as the starting point for conversations and shared treatment decisions with each unique patient. The goal for each of these tools is to encourage appropriate clinical treatment while avoiding the harm of unnecessary treatment. The starting point for such decisions must always be the individual patient**. Tools can help inform how similar patients might fare with a particular course of treatment based on the best available science, but ultimately, the clinician and patient must assess together how to manage that person's health.

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[2] Edmund Anstey D, Li S, Thomas L, Wang TY, Wiviott SD. Race and Sex Differences in Management and Outcomes of Patients After ST-Elevation and Non-ST-Elevation Myocardial Infarct: Results From the NCDR. Clin Cardiol. 2016;39(10):585-595. doi:10.1002/clc.22570

[3] Farmer SA, Kirkpatrick JN, Heidenreich PA, Curtis JP, Wang Y, Groeneveld PW. Ethnic and racial disparities in cardiac resynchronization therapy. Heart Rhythm. 2009;6(3):325-331. doi:10.1016/j.hrthm.2008.12.018

[4] Kumar RS, Douglas PS, Peterson ED, et al. Effect of race and ethnicity on outcomes with drug-eluting and bare metal stents: results in 423 965 patients in the linked National Cardiovascular Data Registry and centers for Medicare & Medicaid services payer databases. Circulation. 2013;127(13):1395-1403. doi:10.1161/CIRCULATIONAHA.113.001437

[5] Chan PS, Rao SV, Bhatt DL, et al. Patient and hospital characteristics associated with inappropriate percutaneous coronary interventions. *J Am Coll Cardiol*. 2013;62(24):2274-2281. doi:10.1016/j.jacc.2013.07.086

[6] Pandey A, Keshvani N, Khera R, et al. Temporal Trends in Racial Differences in 30-Day Readmission and Mortality Rates After Acute Myocardial Infarction Among Medicare Beneficiaries [published online ahead of print, 2020 Jan 8]. JAMA Cardiol. 2020;5(2):136-145. doi:10.1001/jamacardio.2019.4845

[7] Curtis JP, Herrin J, Bratzler DW, Bradley EH, Krumholz HM. Trends in Race-Based Differences in Door-to-Balloon Times. Arch Intern Med. 2010;170(11):992–993. doi:10.1001/archinternmed.2010.165

[8] Bradley EH, Nallamothu BK, Herrin J, et al. National efforts to improve door-to-balloon time results from the Door-to-Balloon Alliance. J Am Coll Cardiol. 2009;54(25):2423-2429. doi:10.1016/j.jacc.2009.11.003

[9] Krumholz HM, Herrin J, Miller LE, et al. Improvements in door-to-balloon time in the United States, 2005 to 2010. Circulation. 2011;124(9):1038-1045. doi:10.1161/CIRCULATIONAHA.111.044107

Most risk prediction models used in clinical care are rendered as either web- or app-based calculators and require between five and 10 clinical and demographic variables. No model, certainly not relatively simple ones intended to guide point-of-care treatment, can ever fully predict the clinical future of an individual patient. Furthermore, there are debates in good faith amongst the scientific community as to which models have the best balance of predictive features. These debates often center around a model's accuracy for a given population group—women, for instance, or people of color.

The challenge is that modeling often becomes a zero-sum game: making it more accurate for population A renders it less accurate for population B. Similarly, attempts to make it more accurate for every patient population renders it too complicated to be used practically with any patient population. Like everything in medicine, there are tradeoffs associated with our choices. What is not debated, however, is that **widely utilized risk models are scientific, validated, and clinically very effective for guiding therapy, preferably in a two-way conversation with the patient**. It is worth noting that risk models are published every day in the medical literature, but only a small subset are adjudicated to be sufficiently rigorous and helpful to be used in official ACC guidance and programming.

A relentless drive for self-improvement and the quest for the strongest, most timely science are ingrained in the mission and activities of the College. To that end, we constantly challenge ourselves to ensure that we are providing the most up to date and relevant scientific information. We will continue to incorporate new, thoroughly vetted scientific data into clinical algorithms as it becomes available. As a scientific and social institution, we also believe that our first responsibility is to acknowledge that these are not easy questions and do not have easy answers. Accepting that our tools and guidelines include tradeoffs and opportunity costs, and then transparently discussing among the scientific, clinical, and patient communities the nature of those tradeoffs, is critical. Furthermore, the core philosophy of the ACC remains focused on the individualization of care, applying the general guidance of our guidelines and tools to the specific circumstances of individual patients. We frequently engage our clinical and scientific community, including under-represented minority clinicians and those that practice in diverse environments, aiming to strike the best balance possible.

The development of advanced mathematical modeling and large-scale, multi-source clinical data sets is revolutionizing how the medical community thinks about prognostic risk in a variety of acute and chronic conditions. In cardiology alone, there are dozens of different models in use to predict long-term likelihood of cardiac events, and thus guide preventive interventions, to manage shorter-term risk, and ultimately to risk adjust clinical outcomes in order to facilitate accurate measurement and quality improvement. While researchers aspire to create causally validated models, wherein each of the independent or predictive variables is biologically or mechanistically linked to the outcome in question, the complexity of human pathophysiology often intervenes. Furthermore, to be practical in a clinical setting, risk prediction models need to be parsimonious in their construction, using relatively few and easily accessible predictive variables. The result is that most frontline clinical models rely on inputs that "carry" additional information through mathematical correlation, not physiological causation. This is particularly the case when models attempt to account for social

determinants of health, well-documented to account for as much or more variation in outcomes as medical treatment itself.

Some clinical models do include a race variable. One example is the ASCVD Risk Estimator based on the ACC/AHA cardiovascular prevention guidelines. The ASCVD Risk Estimator leverages rigorous population modeling using the Pooled Cohorts Equations and produces a patient's 10-year and lifetime risk estimate for a cardiovascular event, namely a stroke or heart attack. Based on certain thresholds for risk, as established in the guidelines, a clinician may choose to treat the patient with a series of preventive medications, including statins and anti-hypertension medications, as well as counseling the patient on healthy lifestyle choices. **Having previously been aware of the issues described in your letter, the ACC had done a detailed empirical review and evaluation of race and ethnicity impacts in the development of its ASCVD Risk Estimator, resulting in the following guidance to clinicians acknowledging the model's limitations:**

> "These estimates may underestimate the 10-year and lifetime risk for persons from some race/ethnic groups, especially American Indians, some Asian Americans (e.g., of south Asian ancestry), and some Hispanics (e.g., Puerto Ricans), and may overestimate the risk for others, including some Asian Americans (e.g., of east Asian ancestry) and some Hispanics (e.g., Mexican Americans). Because the primary use of these risk estimates is to facilitate the very important discussion regarding risk reduction through lifestyle change, the imprecision introduced is small enough to justify proceeding with lifestyle change counseling informed by these results."

While the cautions are important, the decision was made to retain the race variable in the ASCVD Risk Estimator because it materially enhances the accuracy of the overall risk estimate for the racial categories included. For example, selecting Black in the ASCVD Risk Estimator accurately increases the patient's 10-year and lifetime risk of a cardiovascular event in accordance with the well-reported scientific literature.

The ACC also recognizes the dilemma of this variable. On one hand, it is generally acknowledged that racial variables often also reflect social, demographic, and economic determinants of health. We know that biology does not sufficiently vary across race to explain the difference in observed cardiovascular outcomes in the United States. On the other hand, it reflects the unfortunate truth that Black Americans, controlling for a host of other clinical variables such as cholesterol and blood pressure, still endure a higher risk of having a heart attack or stroke. Capturing that risk in the ASCVD Risk Estimator is intended to alert both clinicians and patients to that population risk, potentially resulting in a more aggressive treatment strategy to manage that risk as it manifests in the individual patient. From that perspective, one could argue the inclusion of the race variable draws attention to disparities in outcomes and proactively focuses attention on patients that are indeed at the highest risk. In the ASCVD risk model, the race variable is efficient in the sense it is easy for a patient or clinician to assess and accurately predict risk. **Still, we are committed to ongoing monitoring of the model, consideration of iterative revisions, and feedback on its use in clinical practice.**

The dilemma of race variables in predictive models is illustrative of the dual responsibility of the cardiovascular clinician to address the consequences of racial and structural injustice and its manifestation in

health disparities. The clinician's first obligation is to provide the best possible care to each patient. Patients present bearing the burdens of society as it is, not as we wish it to be. By understanding how these social burdens manifest as clinical risk, clinicians can endeavor to attenuate that risk at the individual patient level. However, the ACC also believes it has a responsibility to address the structural drivers of this disparity, with the ambition of reducing the variation in risk across race by reducing the social and structural disparities which drive it. Our work to address structural disparity is described in other portions of this letter.

The ultimate goal of the ACC is to equip clinicians and patients with as much information as possible to guide the development of a shared, effective care plan. The ACC/AHA guidelines repeatedly emphasize the importance of shared decision making, wherein the clinician and patient discuss the goals and risks of treatment and customize a care plan that accounts for the values of the patient. Under such a model of care, the ASCVD Risk Estimator and other models like it are but one input in a comprehensive process of assessing and managing cardiovascular risk.

Policy Implications and Considerations Moving Forward

The ACC has actively developed quality improvement initiatives to focus care on evidence-based approaches using objective clinical variables that can help close racial and ethnicity inequities. Such initiatives have focused on discharge medications, timely heart attack care (as previously noted), and reducing heart attack risk. Optimizing care for patients has always required the best objective science combined with the art of clinical decision making for individual patients.

Recent efforts by the College to examine the influences of race and ethnicity on care have included a retrospective data analysis and publication of LDL cholesterol treatment patterns. Published as an abstract at the 2019 AHA Scientific Sessions, the analysis found that Black individuals were less likely to have achieved LDL treatment thresholds to reduce future heart attacks than Whites. Using this information, the College developed a quality improvement initiative using objective science markers to rapidly identify and stratify all patients who had persistent elevated LDL and partner with eight practices throughout the country to begin lowering patient risk using evidence-based treatments. The results of this intervention, while preliminary, demonstrated a significant reduction in LDL among patients enrolled.

ACC is constantly seeking novel scientific means to better stratify treatments to advance the quality of care for each patient. For example, a new partnership with Cleerly, a technology AI solution for image interpretation, will for the first time allow clinicians to quantify disease and stratify by stage of heart disease within the heart and vessels. By doing so, clinicians and patients will be able to see how medications and interventions directly impact blood flow and risky plaques that cause heart attacks and strokes.

These interventions require access and reasonable co-pays and deductibles for care. ACC has held several meetings to discuss value-based benefit design to ensure that patients and clinicians are supported in the use of the appropriate treatments and interventions. The College believes that the science is available to select the

optimal care for each patient and any barriers impeding access to that care must be minimized. The ACC is committed to partnering with Congress to deliver optimal, value-based health care solutions to every patient.

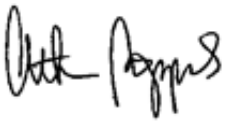
As we continue this conversation, we would be happy to discuss our work and policy proposals that we believe will help improve health equity, including telehealth expansion, increased use of cardiovascular rehabilitation services, and greater awareness of peripheral arterial disease.

In conclusion, a core tenet of the ACC's mission is to equip patients and providers with the highest level of information and facilitate a shared decision-making framework. We constantly strive to improve and refine our efforts to better achieve our mission of transforming cardiovascular care and improving heart health. Ultimately, we must continue to challenge ourselves to improve our performance and the lives of every one of the patients we serve, every day. We sincerely appreciate the role leaders like you play in advancing that imperative.

These are complex topics, and difficult to capture entirely in a letter. It is our sincere hope that this is only the beginning of our conversation and joint efforts to advance our shared goal of achieving health equity. **We look forward to maintaining an open dialogue and finding ways that we can work with you to improve care for all patients. As such, we request the opportunity to meet with your office at your convenience to discuss our above responses in greater detail.**

The College commends you for your efforts to identify and eliminate the drivers of health inequality. For additional questions and to coordinate follow-up, please contact John Kristan, Associate Director for Legislative Affairs, at JKristan@ACC.org or 202-375-6801.

Sincerely,



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