Association of Black Cardiologists, Inc.
Saving the Hearts and Minds of a Diverse America

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ABC MISSION:
To promote the prevention and treatment of cardiovascular disease, including stroke, in Blacks and other minorities and to achieve health equity for all through the elimination of disparities.

May 4, 2021

David Meyers, M.D.
Acting Director
Agency for Healthcare Quality and Research
5600 Fishers Lane
Rockville, MD 20857

Re: Request for Information on the Use of Clinical Algorithms That Have the Potential to Introduce Racial/Ethnic Bias Into Healthcare Delivery

Dear Dr. Meyers:

On behalf of the Association of Black Cardiologists (ABC), we thank the Agency for Healthcare Quality and Research (AHRQ) for its decision to commission an evidence review on commonly used algorithms, including whether race/ethnicity is included as an explicit variable, and how algorithms have been developed and validated. The ABC is pleased to respond to your call for information.

Founded in 1974, the ABC is a nonprofit organization with a national and international membership of 2,023 cardiovascular specialists, cardiologists in training and other health professionals, as well as professionals outside of health care who are members of the community (Community Health Advocates) and corporate and institutional members. The ABC is dedicated to eliminating disparities related to cardiovascular disease for all people of color and adheres to the vision that all people regardless of race, ethnicity or gender should benefit equally from reduction in the frequency, duration and impact of diseases of the heart and blood vessels.

In 2007, ABC member Clyde W. Yancy, MD, MSc, MACC, FAHA, MACP, FHFSA wrote:

"Race is neither physiologic nor scientific; rather it is a social construct that reflects a group of persons with shared ancestry and similar customs/lifestyles that also intermarry. Clearly, African Americans represent a heterogeneous group and there is no reason to believe that any single genetic trait is uniformly and exclusively distributed in African Americans. Race is not a proxy for genetics and any effort to ascribe such is shallow and lacking in understanding. However, within a group, it is conceivable that certain traits may be overrepresented and that these traits might contribute to disease."[1]

[1] The Association of Black Cardiologists Responds to "Race In A Bottle": A Misguided Passion; July 30, 2007. https://www.scientificamerican.com/article/the-association-of-black-cardiologists-responds-to-article/

More than 13 years later, racial bias remains pervasive throughout medicine, influencing medical decision making, quality of care and outcomes. The coronavirus pandemic has spotlighted racial and ethnic health care inequities and has, consequently, created an opportunity for meaningful policy reform. At the core of racial bias in medicine is structural racism. If the contributors to structural racism are not adequately addressed, it will be more difficult to address all its downstream effects. Furthermore, communities without access to digital technology and services are disadvantaged by the digital divide which is widening with the apparent shift toward telehealth, remote patient monitoring and the delivery of health care interventions using digital technology. Access to digital tools and digital literacy are social determinants of health.[2] As such, efforts need to be directed toward assessment of digital literacy and tailored patient education when accessing health care and through community-based programs.

Advances in health care have established the use of evidence-based medicine to guide clinical care. Consistent application of guideline-based care has been clearly demonstrated to eliminate treatment disparities in cardiovascular disease. Health care technology has advanced to incorporate evidence-based medicine and health data into algorithms that support clinical decision making through artificial intelligence (AI). The ABC is pleased to respond to the Agency's request for information with the shared goal of addressing the misuse of race in clinical care algorithms and research.

USE OF CLINICAL ALGORITHMS IN THE DELIVERY OF HEALTH CARE AND THEIR IMPACT ON QUALITY OF CARE, CLINICAL OUTCOMES, QUALITY OF LIFE AND HEALTH DISPARITIES?

Clinical algorithms are critical to population health management.[3] Algorithms and risk prediction models should enable physicians and health systems to anticipate health care needs and allocate resources to improve outcomes for at-risk patients. At the same time, it is essential these algorithms perform equitably. As digital technology becomes more integrated into clinical care, the algorithms will be used more frequently and autonomously to guide patient care. If the data fueling the algorithms are flawed, the output will likewise be flawed as will the resultant patient care. Current health care data reflect underlying disparities. Populations facing socioeconomic barriers to accessing care are underrepresented or misrepresented in our systems. Likewise, current care patterns reflect the biases inherent to the systems collecting the data. Data enable analytics and AI, but we must understand the shortcomings of our data and the social implications of using biased data to drive care decisions. Marginalized populations not included in the data will not reap the full benefits of AI.

The ABC is aligned with the assessment that race has been misinterpreted and misused in clinical care algorithms with consequent harm to communities of color. Much of the misuse may be unintentional and based on the inclusion of faulty data reflecting current inequities into algorithm programming. However, the topic of racism in health care is more deeply rooted and complicated than clinical algorithms alone. Not addressing the inaccurate outputs from clinical algorithms incorrectly programmed to factor race and ethnicity data will lead to perpetuation of disparate care with respect to referral for treatment, allocation of resources and patient satisfaction which may ultimately lead to further disenfranchisement from the health care system through missed treatment opportunities, unfavorable outcomes and failure of treatment adherence.

[2] Sieck CH, Sheon A, Ancker JS, Castek J, Callahan B, Siffer A. Digital inclusion as a social determinant of health. NPJ digital medicine. 2021; 4(1):103.
[3] Obermeyer Z, Powers B, Vogeli C, Mullainathan S. Algorithmic Bias In Health Care: A Path Forward; Nov. 1, 2019. https://www.healthaffairs.org/do/10.1377/hblog20191031.373615/full/

Across virtually every type of diagnostic and treatment intervention, blacks and other minorities receive fewer procedures and poorer quality medical care than whites with similar disease burdens. Although the incentives to use AI algorithms for clinical decision support have worked well for acute care, chronic disease management using AI powered tools (population health management) is fraught with more complexity due to the environmental and social context that are part of patients' lives. In fact, some clinical algorithms for heart failure management artificially raised the risk score for non-blacks which consequently reduced the 'perceived 'severity of blacks resulting in their delayed referral for advanced care.[4] Clinical algorithms are also subject to the inherent implicit biases of the clinicians using them. Research continues to document the persistence of higher implicit bias scores among physicians being associated with biased treatment recommendations and poorer communication in the care of black patients.[5,6] The role of health care providers is to provide context for the algorithm-generated decision during the clinical encounter.

Historical health inequities are embedded in the data used to drive AI algorithms. Health care outcomes are not the same across populations. For example, black women are 42 percent more likely to die from breast cancer. This can be at least partially attributed to factors like a higher burden of co-morbidities and barriers to accessing care that stem from the enduring legacies of structural racism and intergenerational poverty. Black women are also more likely to be diagnosed at later stages of the disease and experience delays in treatment of two or more months. These types of inequitable outcomes are baked into health care data.

Algorithms learn from historical patterns to make predictions and decisions, but if they learn from biased data, they will produce biased outputs. By using biased insights to inform care decisions, systems may unintentionally create or perpetuate inequities. For example, one emerging application of AI is predicting intensive care unit (ICU) demand. Algorithms can be used to identify which inpatients are at risk for clinical deterioration and will require a transfer to an ICU. A model could be built using historical health records of patients who were transferred to ICUs. However, if the training data contains more white than black patients, the model will make better predictions for white patients. Deterioration might be underestimated for black patients, leading to fewer transfers and worse outcomes.

Other examples of clinically significant algorithmic bias listed in an article published in the *New England Journal of Medicine*[7] demonstrate how improperly programmed algorithms can lead to withholding open heart surgery from black patients when they may be appropriate candidates, and race adjustment for renal function that delay referral for specialist care for transplantation in black patients. Similarly, for many years clinical guidelines incorrectly directed against the use of Tamoxifen in black women with breast cancer based on an underpowered sample of 100 black women in early breast cancer studies.

Data from clinical research are used to create the evidence-based guidelines that power AI engines. If incomplete, inaccurate or data skewed by underlying disparities in clinical trial access are used, then the

[4] Vyas D., et al. (2020) Hidden in Plain Sight-reconsidering the use of race correction in clinical algorithms. NEJM doi: 10.1056/NEJMms2004740
[5] Williams, D. R., Lawrence, J. A., & Davis, B. A. (2019). Racism and Health: Evidence and Needed Research. Annual review of public health, 40, 105–125. https://doi.org/10.1146/annurev-publhealth-040218-043750
[6] Breathett K, Yee E, Pool N, et al. Does Race Influence Decision Making for Advanced Heart Failure Therapies? *Journal of the American Heart Association*. 2019;8. https://doi.org/10.1161/JAHA.119.013592
[7] Obermeyer, Z., et al. (2019). "Dissecting racial bias in an algorithm used to manage the health of populations." Science 366(6464): 447-453.

resultant algorithm outputs will also be skewed. Clinical research is also closely tied to existing clinical guidelines. The inequities programmed into clinical guidelines also appear as inclusion/exclusion criteria which can broaden the data gap by excluding participation of minority patients.

TO WHAT EXTENT ARE USERS OF ALGORITHMS INCLUDING CLINICIANS, HEALTH SYSTEMS, AND HEALTH PLANS AWARE OF THE INCLUSION OF RACE/ETHNICITY OR OTHER VARIABLES THAT COULD INTRODUCE BIAS IN THESE ALGORITHMS AND THE IMPLICATIONS FOR CLINICAL DECISION MAKING?

Users of AI algorithms in health care from patient to clinicians and health systems need to be made aware of the potential for bias in these models. To our knowledge, the extent of this current awareness is unknown. All health care providers (clinicians and health systems), as well as other stakeholders, need to focus on awareness and inclusion as key priorities. Developers of AI algorithms, as well as those who deploy them, need to be intentional in their approach to address bias and ensure that these algorithms are inclusive.

WHAT EVIDENCE IS AVAILABLE ABOUT THE DEGREE TO WHICH THE USE OF CLINICAL ALGORITHMS CONTRIBUTES TO BIAS IN CARE DELIVERY AND RESULTING DISPARITIES IN HEALTH OUTCOMES?

AI has the potential to propagate racial/gender bias, reinforce inequalities and potentially magnify these patterns on a wider scale.

For example, a commercial algorithm used by accountable care organizations was found to be racially biased where Black patients were less likely to be enrolled in care management programs and benefit from its resources.

Another study demonstrated that AI algorithms trained with data that excluded women or had few women performed poorly in diagnosing disease in women.[8] An AI model created by DeepMind (a Google company) using data from the Veterans Affairs hospital included only 6 percent women[9] and has been criticized for its performance in female patient populations.

Particularly compelling is the gender shades study done at the Massachusetts Institute of Technology that demonstrated commercially available facial recognition algorithms to be biased with error rates as high as 35 percent in darker skinned females.[10] Following the publication of these findings, the companies targeted in the study revised their algorithms with subsequent analysis showing improvement whereas a review of other companies not initially evaluated remained biased with high error rates in dark skinned females.[11]

This drives home the point that eliminating bias and inclusion is an intentional process and developers of AI algorithms need to prioritize it. Unfortunately, the AI industry, which is limited largely to a handful of technology companies and university laboratories, suffers from lack of diversity, with women

[8] Larrazabal AJ, Nieto N, Peterson V, Milone DH, Ferrante E. Gender imbalance in medical imaging datasets produces biased classifiers for computer-aided diagnosis. Proceedings of the National Academy of Sciences. 2020;117(23):12592-12594.
[9] Tomasev N, Glorot X, Rae JW, et al. A clinically applicable approach to continuous prediction of future acute kidney injury. *Nature*. 2019;572(7767):116-119.
[10] Buolamwini J, Gebru T. Gender shades: Intersectional accuracy disparities in commercial gender classification. Paper presented at: Conference on fairness, accountability and transparency, 2018.
[11] Raji ID, Buolamwini J. Actionable auditing: Investigating the impact of publicly naming biased performance results of commercial AI products. Paper presented at: Proceedings of the 2019 AAAI/ACM Conference on AI, Ethics, and Society, 2019.

comprising only 15 percent and 10 percent of research staff at Facebook and Google, respectively, while the proportion of Black employees at Facebook and Microsoft is 4 percent and at Google, 2.5 percent.[12]

WHAT ARE APPROACHES TO IDENTIFYING SOURCES OF BIAS AND/OR CORRECTING OR DEVELOPING NEW ALGORITHMS THAT MAY BE FREE OF BIAS?

Removal of race and ethnicity in clinical algorithms alone will not eliminate racial bias in the delivery of medicine. Large databases (such as Mayo Clinic) are used to power AI algorithm engines, if these databases do not contain a sample of representative minorities, an accurate minority experience will not be reflected in the AI output. As such, significant focus is needed on the structural components of racism that give rise to racial inequities.

Education and Training

Diversity in medicine allows patients to connect with their providers on cultural and social levels. Consequently, having more diverse members of our country's physician scientific workforce leads to excellence in patient/population outcomes.

The ABC is leading increasing diversity in the African American cardiology health care workforce.

- In collaboration with historically black colleges and universities (HBCUs) and academic health centers, the ABC supports innovative training programs in clinical cardiology and its subspecialties.

- The ABC works with cardiology training programs to identify black trainees seeking cardiovascular careers and engages medical students by providing mentorship and scholarship opportunities.

- Because ABC members reflect a wide variety of cardiology subspecialties and practice modalities, our cardiologists-in-training are provided with open access to guidance from our experienced cardiovascular specialists.

- ABC recently launched a diversity and inclusion scorecard for academic cardiovascular training programs in the United States published annually in collaboration with several cardiology program directors. The ABC Diversity, Inclusion and Belonging Scorecard seeks to address racial gaps while fostering an inclusive and more diverse cardiology workforce by assessing academic programs utilizing four characteristics: (1) number of underrepresented in medicine (UIM) in general cardiology fellowships; (2) the change in the number of UIM fellows over the life cycle of the of the training program; (3) trainee assessment of a sense of belongingness (i.e. how welcome they feel in that program); and (4) the number of UIM faculty overall, as well as in leadership positions in their cardiology training program. A "traffic light" rating system will evaluate programs as poor, at-risk or excellent based on these four metrics. Rankings will be announced on an annual basis.

- ABC has established the Diversity in Cardiology Award presented to cardiovascular training programs adopting diversity.

[12] West SM, Whittaker M, Crawford K. Discriminating systems. *AI Now*, 2019.

- The ABC Mentor for Youth Program connects medical professionals to youths in high school or college considering a career in medicine.

Data Collection

The ABC believes patient health is heavily influenced by social determinants of health (SODH). Algorithms are often biased because non-clinical factors are not included in their programming. Algorithm accuracy has been improved by incorporating SDOH data. An example from University of North Carolina (UNC) Health System demonstrates how quickly identifying and addressing risks can significantly improve patient outcomes. As part of UNC's population health program, nursing staff would check in with patients at risk of readmission. Due to resource constraints, the staff needed to evaluate how to best focus their efforts on their most high-risk patients. The initial model used length of stay, acuity, co-morbidities, and emergency department visits. UNC partnered with a health analytics firm to build a better model for predicting readmissions. The new "Modern Social Determinants of Health" model did not begin from preconceived theories, but instead used machine learning to ingest and evaluate UNC's data to generate dramatically better predictions of readmission risk. The resulting model takes risk factors into account that are not always intuitive, and it segments the population in ways that are not medically or socially obvious. Despite the "black box" effect, the results were impressive. When compared to more traditional discharge planning rules, the new model correctly predicted twice as many readmissions when 20 percent of the population was targeted for follow-up.[13]

The lack of diversity in data is a long-standing problem the ABC is working to address with the Cardiovascular Implementation Study (CVIS), a practice-based research registry that is integrating social determinants and technology innovation to address health disparities. CVIS is enrolling diverse patients with prioritized health conditions from collaborating ABC member practices, as well as patients from academic health centers and Federally Qualified Health Centers. CVIS prospectively collects socio-demographic and economic data at the point of care. CVIS will evaluate the safety and clinical outcomes of new therapeutic agents, including post-marketing surveillance. CVIS data collection tracks quality of care standards established by the Centers for Medicare and Medicaid Services (CMS) and commercial health plans. Long term, CVIS will become the most comprehensive patient registry for diverse patients with cardiovascular disease and co-morbid conditions by providing real-world data to address health disparities. CVIS will inform cardiovascular algorithms and guide future research that is relevant to diverse populations.

Clinical Trials

The ABC is uniquely qualified to monitor and initiate diversity in cardiovascular care and research. The ABC has created continuing medical education programs that promote evidence-based clinical care supported by practice guidelines. However, practice guidelines and clinical algorithms need robust research databases that reflect the diversity of affected patients and communities. Lack of diversity in clinical trials, as well as racial bias at the point of care, remain a significant barrier to developing effective practice guidelines and the clinical algorithms that rely on them.

[13] Health Care IT Advisor, Advisory Board (2020)The Artificial Intelligence Ecosystem https://www.advisory.com/-/media/project/advisoryboard/shared/research/itsc/research-study/2018/the-artificial-intelligence-ecosystem-2.pdf?rev=f2e253bd71c1425cb6e2bfa92f5355f7&hash=2111637A12128148DCA6D4C1AF391D44

The ABC continually strives to overcome the dearth of clinical data from minority communities. This involves an increased investment in research infrastructure, including trained personnel to increase the recruitment and retention of African Americans and other under-represented patients. The ABC has developed a "train the trainer" mentorship and collaborates with HBCUs, health care provider organizations and research organizations to scale and sustain the clinical research participation of diverse providers and the patients they serve.[14] The lack of clinical data from minority communities is also being addressed through clinical research endeavors such as the African American Heart Failure Trial and participation in ongoing research initiatives sponsored by industry and academia. To control algorithm bias in health care, rigorous validation of clinical data, including vetting in the public domain through publications and scientific symposia, will eventually fuel algorithms and validation of the AI outputs to the target community. Well-constructed AI algorithms may also identify data gaps that compel future research endeavors.

The ABC publicly exposes bias appearing in guidelines and the clinical literature. Recent examples are the rebuttal to the JNC 8 High Blood Pressure Guidelines[15] and the retraction of a racially biased article that appeared in the *Journal of the American Medical Association*.[16] The Association also leads fellow professional organizations, such as the American College of Cardiology and the American Heart Association, to renounce racism in medicine and medical education through joint statements and continuing medical education.[17,18,19] Similar targeted analyses and education through a benchmarking and test-and-learn technique could be used to remove algorithmic bias.

WHAT ARE EXISTING AND DEVELOPING STANDARDS (NATIONAL AND INTERNATIONAL) ABOUT HOW CLINICAL ALGORITHMS SHOULD BE DEVELOPED, VALIDATED, AND UPDATED IN A WAY TO AVOID BIAS?

Racial bias in the delivery of health care is self-perpetuating and begins with the collection of biased health data during the patient's initial encounter with the health care system or researchers. Due to unequal access to health care and clinical studies, minority groups are under-represented in current health services and research datasets. This underrepresentation adversely affects the quality of health services provided to that demographic group since they might be treated according to guidelines informed by data that disproportionately represent people of the majority ethnic or racial group.[20]

The ABC suggests the following strategies:

- Refine algorithms with more data, including SDOH, which can help correct for bias. The ABC CVIS registry uses the National Institutes of Health-developed PhenX Toolkit[21] on social determinants of health to systematically collect sociodemographic data at the point of care. Collection of SDOH measures upstream factors that shape behaviors and health outcomes. PhenX provides a common

[14] Ofili E.O., Schanberg L.E., Hutchinson B.,Sogade F., Fergus I., et al (2019). Int. J. Environ. Res. Public Health 16, 1631; doi:10.3390/ijerph16091631
[15] Wright J., Fine l., et al. 2014 Evidence supporting a systolic blood pressure goal of less than 150 mmHg in patients aged 60 years or older: the minority view. Ann Int Med doi: 10.7326/M13-2981
[16] Kuehn B. (2020) Association of Black Cardiologists Calls for Urgent Effort to Address Health Inequity and Diversity in Cardiology doi: 10.1161/CIRCULATIONAHA.120.050130.
[17] Albert M. Structural Racism and Anti-Blackness in Medicine. https://abcardio.org/structural_racism_medicine/
[18] Lloyd-Jones D., Albert M., Cooper L. et al. Structural Racism as a Public Health Crisis AHA 2020 https://abcardio.org/aha2020/
[19] Albert M., Harrington R., Poppas A. Joint statement on health equity, social justice and civil unrest from the Association of Black Cardiologists, the American Heart Association and the American College of Cardiology AHA Newsroom May 31,2020.
[20] Geneviève, L.D., Martani, A., Shaw, D. et al. Structural racism in precision medicine: leaving no one behind. BMC Med Ethics 21, 17 (2020). https://doi.org/10.1186/s12910-020-0457-8
[21] https://www.phenxtoolkit.org

currency for studying SDOH across public health research studies while allowing researchers to examine the role of SDOH and the factors related to health inequities to identify effective interventions to reduce health disparities. Such standardization of SDOH will allow the CVIS registry to expand its data capacity and predictive modeling by linking with other public health databases. Such analyses will ensure ongoing race, ethnicity and SDOH testing of clinical algorithms.

- "Train" algorithms to predict less biased outcomes and encourage algorithm developers to work with physicians and others closely involved in care delivery to build advanced prediction algorithms. If AI does not code for unintended bias in the development stage, algorithms will perpetuate bias. Bias in, bias out. AI manufacturers and researchers could be required to conduct audits of their predictions before their products ever support a patient.[22] Rigorous validation should assess completeness and quality of data to adequately reflect the community, test relationships between variables, stratify performance results from all angles to identify disparities, and establish a strategy for ongoing performance management.

- Remove registry data collection factors that lead to generalizability of patient outcomes, the consequences of which are profound, including risk prediction scores that misrepresent risk in patients who are excluded.

- Ensure health care costs are not used as a proxy measure for health needs. Algorithms commonly used by health systems and insurance companies, which often use health care expenditures as endpoints, perpetuate existing racial biases.[23] Lower health care costs among underserved and minority populations can be reflective of under-utilization due to access limitations and other factors, including historic medical mistrust by the African American community.[24] The focus of AI algorithms should be on growth over savings.

- Promote partnerships with universities, research centers, agencies and professional organizations to fill data gaps using agile test-and-learn techniques across multiple AI technologies. This will also help assure specialists versed in disparities and health equity are involved in planning, integration and implementation of AI systems. Re-skilling the workforce to integrate AI into workplace processes with an eye toward diversity is a necessity.

[22] Vartan S. Racial Bias Found in a Major Health Care Risk Algorithm Black patients lose out on critical care when systems equate health needs with costs. Oct. 24, 2019. https://www.scientificamerican.com/article/racial-bias-found-in-a-major-health-care-risk-algorithm/
[23] Sokol E. Eliminating Racial Bias in Algorithm Development. Dec. 26, 2019. https://healthitanalytics.com/news/eliminating-racial-bias-in-algorithm-development
[24] Breathett, K., Jones, J., Lum, H.D. et al. Factors Related to Physician Clinical Decision-Making for African-American and Hispanic Patients: a Qualitative Meta-Synthesis. J. Racial and Ethnic Health Disparities 5, 1215–1229 (2018). https://doi.org/10.1007/s40615-018-0468-z

Conclusion

Improving health care equity is a policy imperative. The ABC and its members stand ready to assist the Agency to the fullest extent of our resources and expertise. Questions and requests for additional information should be directed to ABC policy consultant Camille Bonta at cbonta@summithealthconsulting.com or (202) 320-3658.

Sincerely,

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