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David Meyers, MD
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

Dear Dr. Meyers:

On behalf of the American Medical Association (AMA) and its physician and medical student members, I am responding to the Agency for Healthcare Research and Quality's (AHRQ) request for information "Use of Clinical Algorithms That Have the Potential To Introduce Racial/Ethnic Bias Into Healthcare Delivery." The AMA has long recognized that racial and ethnic health inequities are an unjust and major public health reality in the United States. Understanding that race is a social and political construct and not a biological risk factor for disease and death, the AMA has publicly acknowledged that racism impacts public health and is a barrier to effective medical diagnosis and treatment. We share AHRQ's concerns that clinical algorithms may inappropriately incorporate race or ethnicity into its recommendations and believe the efforts of AHRQ's Evidence-based Practice Center (EPC) in identifying algorithms of concern and potential solutions are extremely important in helping to advance equity in health.

Advancing equity in health requires the understanding and acceptance of the harmful impacts of historical and contemporary racism on our individual and collective ability to strive for and achieve a reality in which we all have the resources, conditions, opportunities, and power to thrive and achieve optimal health. The AMA is strongly committed to achieving these goals and addressing such issues is a top priority for our organization. Specifically, we recommend that clinicians and researchers focus on genetics and biology, structural racism, and other structural determinants; and collect, report, and use race data as a proxy for structural racism and not ancestry, when describing risk factors for disease and outcomes. Below, we address certain questions in AHRQ's request, numbered according to how they were numbered in the notice issuing the request.

1. What clinical algorithms are used in clinical practice, hospitals, health systems, payment systems, or other instances? What is the estimated impact of these algorithms in size and characteristics of population affected, quality of care, clinical outcomes, quality of life, and health disparities?

The AMA agrees with AHRQ that gathering additional information on the clinical algorithms in use today and whether they factor race and ethnicity into their calculations and the impact so doing may have on health care is of utmost importance. Collection of additional information on these specific algorithms is an essential early step towards identifying where racism and bias may exist in clinical decision-making tools and how they should be addressed to ensure clinical care and health of historically marginalized communities are not negatively impacted by their application. There are many clinical algorithms in use across health care and among the medical specialties. Given that the approaches in design and implementation, as well as the underlying data provenance, vary, it will be important to seek further input from medical specialty societies and other organizations that have expertise and direct experience with development and use of specific algorithms.

2. Do the algorithms in question 1 include race/ethnicity as a variable and, if so, how was race and ethnicity defined (including from whose perspective and whether there is a designation for mixed-race or multiracial individuals)?

The usage of race and ethnicity as variables, and how both are defined, varies among the clinical algorithms in use today. This is attributable in part to changes in protocols over time, as some of the clinical data registries from which algorithms are derived are more than several decades old. There is also variation among multiple health data systems in *how* the data is collected (are race and ethnicity patient- or investigator/clinician reported) and the number of choices provided to the reporter including options such as reporting mixed-race, "other," or an individual's preference to not report. Furthermore, because race is a social construct, there is significant variability in how "races" are defined by society, lawmakers, and others. These definitions have changed and evolved in usage and application over time. Accordingly, their inclusion as variables creates challenges in developing meaningful consensus definitions, especially as our society diversifies over time, further clouding how we define these variables.

3. Do the algorithms in question 1 include measures of social determinants of health (SDOH) and, if so, how were these defined? Are these independently or collectively examined for their potential contribution to healthcare disparities and biases in care?

The AMA defers to the stewards of the data and data platforms (e.g., electronic health record systems; clinical data registries) to provide information as to the degree to which SDOH are collected, applied, and examined during the development and implementation of clinical algorithms. The AMA is actively engaged in the Gravity Project, which was created to develop FHIR-based standards to capture and exchange SDOH information.[1]

5. For the algorithms in question 1, what approaches are used in updating these algorithms?

Medical societies and related organizations are taking action to address concerns associated with the **potential for racist and/or biased** clinical algorithms. For example, the American Society of Nephrology (ASN) and the National Kidney Foundation (NKF) have formed a task force to review and reconsider the inclusion of race in the estimated glomerular filtration rate (eGFR).[2] The current algorithm for eGFR has been called into question for its inclusion of a "correction" for Black patients that estimates a higher kidney function than non-Black patients.[3] Not only is the science that this adjustment is based on questionable, but because the algorithm erroneously overestimates kidney function for Black patients, it may improperly lead to delays in and withholding of care. The stated goal of the ASN and NKF task force is to ensure that the eGFR tool provides an "unbiased assessment of kidney function so that laboratories, clinicians, patients, and public health officials can make informed decisions to ensure equity and personalized care for patients with kidney diseases." Efforts like this one, involving stakeholders from medical societies, patient organizations, and related specialists, can provide insights and a potential framework for the meaningful review of clinical algorithms and their potential for perpetuating medical racism and bias in clinical decision-making.

The AMA is also mindful of advances in scholarship (e.g., public health, critical race theory, and social epidemiology) which call for a shift from thinking of race as a biological risk factor for disease to a deeper understanding of racism as a determinant of health. Thoughtful reconsideration must include an

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[1] http://www.hl7.org/gravity/.

[2] https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/20.9.25%20ASN%20Response%20to%20Chairman%20Neal%20re%20Race%20and%20eGFR.pdf.

[3] Vyas DA, Eisenstein LG, Jones DS. Hidden in plain Sight—reconsidering the use of race correction in clinical algorithms. *N Engl J Med*. 2020 Aug 27;383(9):874-82.

examination of the underlying social conditions that contribute to health outcomes, including how systemic racism has created and shaped such social conditions as failure to address and remedy social risk factors will hinder efforts to reduce and eliminate the health inequities long associated with racism and discrimination. While this review is underway, clinicians should be encouraged to use their clinical judgment to determine if race correction is warranted, and thoughtfully consider if they may improve or exacerbate inequities for individual patients and populations.[4]

The AMA House of Delegates in November 2020 passed new policy directing our organization "to collaborate with appropriate stakeholders and content experts to develop recommendations on how to interpret or improve clinical algorithms that currently include race-based correction factors."[5] The AMA is currently undertaking an effort to convene a variety of organizations to gather more information about the use of clinical algorithms and create an action plan for how to address these problems. The AMA looks forward to supporting, encouraging, and coordinating its efforts with these organizations to both better understand the algorithms in use today and how they can be improved upon to ensure they help drive equitable care.

We believe that, in addition to efforts like our own, AHRQ is ideally situated to conduct and fund additional research into the use of race and ethnicity data in clinical settings and algorithms, their potential contribution to medical racism and/or bias in clinical decision-making, and the methods needed to eliminate such racism and/or bias.

6. Which clinical algorithms have evidence that they contribute to healthcare disparities, including decreasing access to care, quality of care or worsening health outcomes for Black, Indigenous, and other people of color? What are the priority populations or conditions for assessing whether algorithms increase racial/ethnic disparities? What are the mechanisms by which use of algorithms contribute to poor care for Black, Indigenous, and other people of color?

Perhaps the most well-known example of an algorithm that contributed to inequitable care is the Optum algorithm which used health care cost as a proxy for health, resulting in lower risk scores being assigned to Black patients who were equally sick to similarly situated white patients.[6] While assigning higher risk scores to patients who have higher health care costs may have seemed reasonable to the developers because higher health costs are often associated with greater needs, doing so failed to account for the systemic and long-standing inequities in care that have resulted in fewer expenditures on Black patients. This resulted in further inequitable care, including excluding black patients from care management programs that dedicate additional resources to coordinate care for higher risk programs.

The use of race or ethnicity in clinical algorithms used in cardiology, nephrology, obstetrics, and urology, among others, have been questioned and subjected to close scrutiny. The recent reviews of the questionable use of race and ethnicity in these algorithms has led to efforts to reassess the use of such data by a variety of related groups.[4] While these reviews are ongoing, it is clear that a comprehensive assessment of the use of race and ethnicity data in clinical algorithms is vital to understand the extent of current use and ensure that their inclusion does not re-enforce pre-existing inequities in care.

Importantly, highlighting the questionable use of race and ethnicity in clinical algorithms has led to an opportunity to re-consider the impact of clinical algorithms broadly and focus attention on where

[4] Id.
[5] Racial Essentialism in Medicine D-350.981, https://policysearch.ama-assn.org/policyfinder/detail/algorithm?uri=%2FAMADoc%2Fdirectives.xml-D-350.981.xml.
[6] Obermeyer et al, "Dissecting racial bias in an algorithm used to manage the health of populations," *Science* (Oct 25, 2019), https://science.sciencemag.org/content/366/6464/447.

additional research is needed. In addition to gathering known examples of clinical algorithms, it is essential to identify where gaps in knowledge continue to exist. It is clear, for example, that investigation into algorithmic bias can be hampered by the fact that many algorithms used in artificial intelligence (AI)-driven platforms are proprietary, with a lack of transparency on the data sets and information underlying their output.[7] It is also necessary to consider the role training data plays in contributing to clinical algorithmic bias. Researchers are starting to identify errors in commonly used machine learning training datasets. One study conducted by computer scientists from the Massachusetts Institute of Technology found that 3.4 percent of the data was inaccurate or mislabeled.[8] Discrepancies in the quality and accuracy of training data can manifest itself in algorithmic system use. Implicit bias may contribute to human mislabeling practices and subsequent training data sets. This is particularly concerning when using trained algorithms in health care settings or in conjunction with other AI tools or services.

As described above, and in response to resolutions passed by the AMA House of Delegates in November 2020, the AMA is undertaking an effort to convene a variety of organizations to gather more information about the use of clinical algorithms and create an action plan for how to address these problems. We believe that in addition to efforts like our own, AHRQ is ideally situated to conduct and fund additional research into the use of race and ethnicity data in clinical settings and algorithms, their contribution to health inequities, and the methods needed to eliminate bias.

7. 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? 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? To what extent are patients aware of the inclusion of race/ethnicity or other variables that can result in bias in algorithms that influence their care? Do providers or health systems communicate this information with patients in ways that can be understood?

It is likely that some but not all users of algorithms, including clinicians, health systems, and health plans, are aware of the inclusion of race/ethnicity or other variables. The AMA does not have any evidence of its own to know the degree to which users of these algorithms are aware that inclusion of those variables could introduce bias and have implications for clinical decisions. Clinicians who input the data required by the algorithm to produce an output may or may not realize that this could contribute to biased results. Clinicians depend on the developers, some of which are the specialty societies to which they belong, to validate the clinical algorithms.

Patients have a fundamental right to know the risk, benefit, indications, and alternatives, including to not proceed, of any health care intervention that they are considering, and physicians have a fundamental obligation to ensure their patient's consent to care is well-informed. Yet, most patients have no idea when an algorithm is being used to inform their care or provide possible treatment options. They are not aware of the types of variables—including race or ethnicity—that go into clinical algorithms, what those variables truly represent, and what impact those variables may have on their care. Furthermore, they may not be aware of if and when their data is used to contribute to the development of AI and machine learning tools. Additionally, as medicine grapples with questions of whether and how to best inform individuals of the use of algorithms, AI, and machine learning tools in their care delivery, we note that the AMA's Privacy Principles state that individuals should have the right to know whether their data will be used to develop and/or train machines or algorithms.[9] The opportunity to participate in data collection for

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[7] Id.
[8] https://www.engadget.com/mit-datasets-ai-machine-learning-label-errors-040042574.html.
[9] https://www.ama-assn.org/system/files/2020-05/privacy-principles.pdf.

these purposes must be on an opt-in basis. We encourage AHRQ to urge Congress to adopt these concepts into any forthcoming federal privacy legislation.

8. What are approaches to identifying sources of bias and/or correcting or developing new algorithms that may be free of bias? What evidence, data quality and types (such as claims/utilization data, clinical data, information on social determinants of health), data sources, and sample size are used in their development and validation? What is the impact of these new approaches and algorithms on outcomes?

To ensure appropriate care for patients who may not have received it, perhaps because health care decisions were based at least in part on the output of a clinical algorithm, an individual's clinical status and therapeutic options can be reviewed and revised as appropriate during their follow-up evaluation and management visits. If risk calculators are used, clinicians could adopt an approach similar to the example given by the authors of the *New England Journal of Medicine* article[10] for coronary bypass surgery, changing what is entered for race and ethnicity into the algorithm, and discussing with the patient any observed differences in absolute risk that might be based on race. In most clinical situations, what matters most to patients, their families, and physicians is the absolute risk of any proposed intervention. A similar exercise applied on a population basis could provide insights as to sources of bias.

Medical specialty societies and other organizations that have expertise and direct experience with development and use of specific algorithms will be critical to developing recommendations on how to identify, interpret, and improve clinical algorithms that currently include race-based correction factors. Changing the types of data used to train algorithms and the labels of such data may be one way to reduce racial bias in clinical algorithms; however, ensuring such labels are consistent with patient self-identification and do not exacerbate inequities requires "in-depth understanding of how structural discrimination operates in society," which may not be front of mind—or within the expertise of—all health researchers and clinicians.[11]

Some scholars note that attempts to make algorithms "race neutral" by eliminating race as a variable are insufficient; rather, researchers must "anticipate the structural bias in a dataset or the social implications of a product" and take a "proactive, explicitly anti-racist approach to data collection, analysis and prediction."[12] As an overarching matter, to best prevent and combat the influences of racism and bias in clinical algorithms, we specifically recommend that genetics and biology, the experience of racism, and social determinants of health—not race—be used in clinical algorithms contemplating disease risk factors. As has been found in the reassessment of measures of renal function, the substitution of one biomarker, serum creatinine, by another (cystatin) has the potential to eliminate the inherent bias when serum creatinine levels are inappropriately adjusted based on race. It would advance efforts to eliminate race from clinical algorithms if AHRQ is able to identify similar alternative variables.

10. 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? Are you aware of guidance on the inclusion or race/ethnicity, related variables such as SDOH, prior utilization, or other variables to minimize the risk of bias?

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[10] Vyas DA, Eisenstein LG, Jones DS. Hidden in plain Sight—reconsidering the use of race correction in clinical algorithms. *N Engl J Med*. 2020 Aug 27;383(9):874-82.

[11] Owens, K., Walker, A. Those designing healthcare algorithms must become actively anti-racist. *Nat Med* 26, 1327–1328 (2020). https://doi.org/10.1038/s41591-020-1020-3.

[12] Id.

There are many existing and developing standards. Specifically, three existing standards, CONSORT, SPIRIT, and TRIPOD-ML are referenced by a developing standard, MINIMAR (MINimum Information for Medical AI Reporting), by Hernandez-Boussard, et al.[13] CONSORT is Consolidated Standards of Reporting Trials (25-item) for clinical trials. PIRIT is Standard Protocol Items: Recommendations of Intervention Trials (33-item) and is a checklist for interventional trials. These two standards will be extending their checklist to include guidelines for machine leaning (ML) AI components, which will complement a new initiative from TRIPOD, TRIPOD_ML, the Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis and Diagnosis for Machine Learning. MINIMAR is feeding into these initiatives and is proposed to be adopted as a standard. It will help the dissemination of algorithms across health care systems and provide transparency to address potential biases and unintended consequences.

The clinical algorithms should be created based on data collected in a "datasheet for datasets." A new format to collect such data is presented as a "Data Nutrition Label format" by Holland, et. al.[14] Data is a fundamental ingredient in algorithms, clinical decision support and AI; the quality of a dataset used to build a model directly influences the results it produces. The nutrition label format caters to a wide range of requirements for and information available from a specific dataset. During label generation and subsequent updates, it also accommodates data specialists of different backgrounds and technical skill levels to select and to prompt data analysis, development, and validation. The label is built with scalability in mind, and with an eye towards standardization. It provides flexibility for dataset authors and publishers to identify the "right" kind and amount of information to include in a label; over time, this could become a set of domain-specific best practices.

11. To what extent are users of clinical algorithms educated about how algorithms are developed or may influence their decision making? What educational curricula and training is available for clinicians that addresses bias in clinical algorithms?

The AMA believes it is vital that all providers understand how the clinical algorithms they rely on to provide appropriate and equitable care in practice are developed. The need for such understanding is particularly acute as to how algorithms developed using artificial intelligence are trained in order to understand the appropriate uses for and limitations of such algorithms. Having this understanding will help ensure appropriate utilization of algorithms and encourage effective oversight by regulators, providers, and others. Over-reliance on any algorithm, particularly without an understanding of what its most effective uses are, can create a risk for amplifying and perpetuating biases that are present in the data, including any bias based in race or ethnicity.

The AMA expects that physicians will turn to their usual trusted sources of clinical information in their field, most commonly their specialty societies. The AMA already has formal agreements with several of the societies to jointly develop educational content and can reach out to them for this purpose. Through the societies and the AMA, physician awareness can be increased as to the strengths and limitations of clinical algorithms, how they can be best applied to patient care, and how to communicate nuanced information to patients. As specialty societies and physicians caring for patients focus on risk assessment of individuals, important contributions will be made by the public health community as it continues to focus on measuring risk at the population health level using instruments such as community health needs

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[13] Hernandez-Boussard, Tina, Bozkurt, Selen, Ionaidis, John P. A., Shah, Nigam H, "MINIMAR (MINimum Information for Medical AI Reporting): Developing reporting standards for artificial intelligence in health care," Journal of the American Medical Informatics Association, Volume 27, Issue 12, December 2020, pages 2011-2015, https://academic.oup.com/jamia/article/27/12/2011/5864179.

[14] Holland, S., Hosny, A., Newman, S., Joseph, J., & Chmielinski, K. (2018). The Dataset Nutrition Label: A Framework To Drive Higher Data Quality Standards. *ArXiv, abs/1805.03677*, https://arxiv.org/ftp/arxiv/papers/1805/1805.03677.pdf.
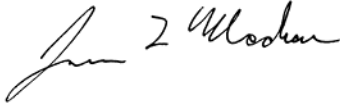
assessments. Social epidemiologists will be focusing on measuring health inequities (e.g., excess deaths, mortality rate ratios). Estimates of individual, community and population level risk will all benefit when race and ethnicity data are no longer used as proxies for the actual contributors to risk such as racism, health inequities, and social risk factors.

Sincerely,

James L. Madara, MD