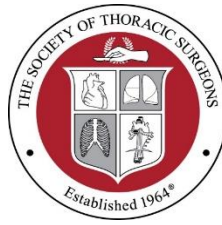


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March 8, 2023

Dr. Robert Otto Valdez, Ph.D., M.H.S.A.
Director
Agency for Healthcare Research and Quality
5600 Fishers Lane
Rockville, MD 20857

Re: Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare

Dear Director Valdez,

On behalf of The Society of Thoracic Surgeons (STS), I write to provide comments on the Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare report issued by the Agency for Healthcare Research and Quality (AHRQ). Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,600 surgeons, researchers, and allied health care professionals worldwide who are dedicated to ensuring the best possible outcomes for surgeries of the heart, lungs, and esophagus, as well as other surgical procedures within the chest.

On February 9, AHRQ published a draft report Impact of Healthcare Algorithms on Racial and Ethnic Disparities in Health and Healthcare. The objective of the report is to examine the evidence on whether and how healthcare algorithms (including algorithm-informed decision tools) exacerbate, perpetuate, or reduce racial and ethnic disparities in access to healthcare, quality of care, and health outcomes.

The report examines two Key Questions (KQs).

- 1. KQ 1 explored the effect of healthcare algorithms on racial and ethnic disparities in access to care, quality of care, and health outcomes.*
- 2. KQ 2 identified strategies to mitigate racial and ethnic bias associated with algorithms.*

KQ 1 studies found that algorithms can reduce racial and ethnic disparities, perpetuate or exacerbate disparities or have no effect on disparities. The studies examining algorithms that included race and ethnicity as an input variable all reduced disparities.

Studies addressing KQ 2 examined algorithms that perpetuated or exacerbated racial and ethnic disparities, thereby warranting mitigation strategies. Algorithms that perpetuated or exacerbated disparities spanned many clinical applications, including kidney function measurement (e.g., estimated glomerular filtration rate [eGFR]), cardiovascular risk assessment (e.g., atherosclerotic cardiovascular disease algorithms), lung function measurement (e.g., Global Lung Function Initiative algorithms), and anticoagulation titration (e.g., warfarin dosing algorithms).

STS is deeply committed to the elimination of bias and disparities in healthcare in general and specifically in cardiothoracic surgery. Equitable access to cardiothoracic surgical care is fair, just, and contributes to optimal patient outcomes across all patient demographics. In this context, STS appreciates the goal of AHRQ to better understand how the use of clinical algorithms (which we refer to technically as risk models) can affect racial and ethnic disparities in healthcare. We would like to use this opportunity to highlight the principles STS uses in developing risk models in cardiothoracic surgery, our experience with these models over several decades of use, and the contemporaneous marked improvements in access and outcomes we have observed for racial and ethnic minorities.

STS developed the STS National Database in 1989 as the foundation of our efforts to improve quality and patient safety among cardiothoracic surgeons. The Database has four components, each focusing on a different area of cardiothoracic surgery—Adult Cardiac Surgery, Congenital Heart Surgery, General Thoracic Surgery, and Mechanical Circulatory Support. Currently, the Adult Cardiac Surgery Database (ACSD) alone contains more than 7 million cardiac surgery procedure records and has more than 3,800 participating physicians, including surgeons and anesthesiologists, representing more than 95% of all adult cardiac surgery hospitals and practices across the United States.

The STS National Database was developed so that cardiothoracic surgeons could collect and analyze the relevant and necessary data for risk-adjusted quality measurement and improvement initiatives. It also provides useful tools for cardiothoracic surgeons and the public, such as the [STS Short-Term Risk Calculator](#). This Risk Calculator allows surgeons and other users to calculate a patient's risk of mortality and complications for the most commonly performed cardiac surgeries. It is based upon STS risk models—statistical tools that account for the impact of patient risk factors on operative mortality and morbidity.

Risk models developed by the STS Quality Measurement Task Force (QMTF) are used to inform surgical decision-making and operative consent decisions with patients; to guide quality improvement; and to estimate provider performance compared to national benchmarks. In addition to its feedback value for hospitals and surgeons, provider performance reports are also the basis of the STS voluntary [public reporting program](#), which emphasizes composite outcomes measures and is the most extensive and detailed public report card produced by any healthcare specialty. These performance measures incorporate STS risk models, which typically include demographic, clinical, and social risk variables, and a functional variable will soon be added. Their goal is to account for all factors not under the control of the provider that may be associated with differences in patient outcomes, thereby isolating the effect of provider quality.

In the development of risk models, STS has specifically considered multiple published recommendations regarding social risk (including sociodemographic status [SDS] and socioeconomic status [SES], race, and ethnicity), as well as the findings of STS data analyses. Consistent with recently published [recommendations](#) by the National Quality Forum (NQF), we also assess the predictive accuracy of STS risk models with and without the inclusion of social risk variables, both overall and within relevant population subgroups (eg, racial or ethnic minorities). Although specific recommendations from different organizations and authors may vary, we have developed and promulgated STS risk model development guidelines based on several generally accepted principles. As published in 2022 ^{1,2}, these include:

1. Direct and indirect causal pathways by which social risk might be associated with outcomes will be described, recognizing that for many if not most healthcare risk variables, the causal mechanism is incompletely understood.
2. If social risk variables are postulated to be associated with outcomes and are not included in risk models, the specific reasons for and potential effects of their omission will be discussed.
3. If racial and/or ethnic variables are included, risk model descriptions will acknowledge the substantial heterogeneity that exists within self-identified or even ancestry-based racial categories. Any race associations should be viewed “on average”, which is also true of most other clinical or social risk variables. The rationale for inclusion of race or ethnicity variables will be explicitly discussed, as it has been in current STS risk model publications.^{1,2}
4. Available social risk variables (including missing %), will be described.
5. Exploratory analyses will be conducted with various combinations of social risk indicators (e.g., SDS/SES status, race, ethnicity), acknowledging that SDS/SES, as well as discrimination, may account for some of the apparent association of race with health outcomes. Any analyses of model performance, including but not limited to model calibration and discrimination, should be performed in the overall population and in the relevant SDS/SES, race, and ethnic populations (e.g., model performance in the estimation of stroke, overall and among Black patients, with and without the inclusion of race, and with or without concomitant inclusion of other SDS/SES variables).
6. As they become generally available, more specific SES/SDS and genetic indicators for individual patients will be substituted, including those related to race and ethnicity (e.g., genetic polymorphisms or mutations that confer increased or decreased risk, and potentially actionable mutations such as those identified in various cancers). Continued inclusion of some current SDS/SES, race, or ethnicity variables may be unwarranted if their association with an outcome is fully explained by new and more specific risk factors with a more proximal and direct association.
7. Whether or not SDS/SES, race, or ethnicity variables are included in risk models, stratified analyses and feedback reports using these categories will be presented, which are more likely to explicitly demonstrate disparities in outcomes. Various approaches to stratification are available, and the most appropriate option(s) should be selected depending on the goal (e.g., within-provider stratification of outcomes by SDS/SES status or race; stratified between-provider differences in outcomes; or national outcomes stratified by SDS/SES, race, or ethnicity).
8. Language has been added to the STS risk calculator indicating that these estimates are only one of several sources of information to be used in cardiothoracic decision-making and patient

¹Shahian, David M., Vinay Badhwar, Sean M. O’Brien, Robert H. Habib, Jane Han, Donna E. McDonald, Mark S. Antman et al. “Social Risk Factors in Society of Thoracic Surgeons Risk Models. Part 1: Concepts, Indicator Variables, and Controversies.” *The Annals of Thoracic Surgery* (2022)

²Shahian, David M., Vinay Badhwar, Sean M. O’Brien, Robert H. Habib, Jane Han, Donna E. McDonald, Mark S. Antman et al. “Social Risk Factors in Society of Thoracic Surgeons Risk Models Part 2: Review of Empirical Studies in Cardiac Surgery and Risk Model Recommendations.” *The Annals of Thoracic Surgery* (2022).

counseling. Other sources include but are not limited to the clinical judgment of the surgeon, referring cardiologist, and PCP, and patient and family preferences. Most importantly, it states that risk calculators should not be used to exclude patients from surgery based on higher risks associated with any single clinical or social risk factor (e.g., BMI, kidney disease, sex, race, ethnicity, payer).

9. Potential unintended adverse consequences of including or excluding social risk factors in risk models will be explicitly discussed, and mechanisms implemented to monitor and mitigate them.

Using audited national data from the STS National Database and various STS risk models, we have performed extensive cross-sectional and longitudinal studies on the use of racial or ethnic data in our clinical algorithms. As documented in our recent publications^{1,2}, these studies have revealed that the accuracy of some STS risk models would be significantly degraded if a race variable were excluded, even if other markers of socioeconomic status were included. Thus, without race in these models, patients, providers, and other stakeholders would knowingly be given inaccurate information for shared decision-making and provider quality assessment. This is a major reason we continue to include race and ethnicity in many of our risk models.

Access to healthcare, especially specialty care like cardiothoracic surgery, is key to reducing inequities and disparities, and we have extensively studied this key quality indicator. Regarding your Key Question 1 (KQ 1), longitudinal studies² over the period 2008 - 2018 have shown dramatic increases in the proportion of Black, Asian, Native American, Hawaiian/Pacific islander, and Hispanic patients receiving major adult cardiac surgical procedures and corresponding decreases in the proportion of White patients. Further, longitudinal studies of STS major adverse outcomes (ie, death and major complications) over the period 2008 – 2019 have shown equivalent or greater reductions in postoperative mortality and morbidity for Black patients compared with White patients, with a narrowing (although persistent) racial gap in these outcomes. Overall, these findings show both dramatic longitudinal increases in access for Black and other minority populations, as well as *outcomes improvements* that are at least as large, and in some cases larger, than comparable improvements for White patients. We believe these findings are consistent with a positive impact on minority access and outcomes of the STS's nationally regarded quality program, the foundations of which are its clinical Database and its portfolio of comprehensive risk models that incorporate both clinical and social risk factors.

With careful attention to appropriate methodological principles, acknowledgment of limitations, and monitoring and mitigation of potential unintended negative consequences, STS will continue to judiciously and selectively incorporate social risk factors, including race and ethnicity, in its risk models. This will optimize the accuracy of risk estimates for patient counseling and shared decision-making, quality improvement, detection and remediation of disparities, provider performance classification, and public reporting. Updated and more specific social risk indicators will be substituted as they become available.² STS will also continue to study stratified results for various socially vulnerable populations, including racial and ethnic minorities, to assure that their access to cardiothoracic care and outcomes continue to improve.

² Shahian, David M., Vinay Badhwar, Sean M. O'Brien, Robert H. Habib, Jane Han, Donna E. McDonald, Mark S. Antman et al. "Social Risk Factors in Society of Thoracic Surgeons Risk Models Part 2: Review of Empirical Studies in Cardiac Surgery and Risk Model Recommendations." *The Annals of Thoracic Surgery* (2022).

Thank you for the opportunity to provide these comments. Please contact Molly Peltzman, Associate Director of Health Policy, at mpeltzman@sts.org or 202-787-1221 or Derek Brandt, Vice President of Government Affairs, at dbrandt@sts.org or 202-787-1223 should you need additional information or clarification.

Sincerely,

A handwritten signature in black ink, reading "Thomas E. MacGillivray". The signature is written in a cursive style with a large, prominent initial 'T'.

Thomas E. MacGillivray, MD
President