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December 18, 2020
Chairman Richard E. Neal
Committee on Ways and Means
U.S. House of Representatives
Washington, DC 20515

Dear Chairman Neal:

Thank you for your November 24 letter regarding The Society of Thoracic Surgeons predictive risk models. Unfortunately, we did not receive the letter until December 8. We appreciate you extending your deadline for our reply so that we would have an opportunity to provide a more thorough response.

We share your commitment to ensuring all Americans have access to the best possible health care, and we look forward to working with you in pursuit of that goal. In this response, we will directly answer the specific questions you have posed at the end of your letter. We will also address other issues in your letter that may reflect misinterpretation of how STS risk models are used. Respectfully, we are even concerned that some of your well-intentioned recommendations might, unintentionally, actually be more likely to harm minority and other vulnerable patient populations rather than help them, and that they might penalize and disincentivize the very programs who care for disproportionate numbers of these patients.

Founded in 1964, The Society of Thoracic Surgeons is a not-for-profit organization representing more than 7,500 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. For decades we have been the leader among healthcare professional societies in measuring quality, in assessing the comparative performance of our participating cardiothoracic surgical programs, and in voluntary public reporting. Regarding the later, we began public reporting of detailed outcomes measures in September 2010, and roughly 80-90% of adult and pediatric cardiac participants in our STS Database voluntarily allow their data to be published on our internet site (https://publicreporting.sts.org/). No other professional society provides such detailed outcomes data to the public.

Our members participate in voluntary public reporting because they trust the scientific validity of our performance measures and the statistical models that adjust for the inherent risk of patients. These STS risk models are critical to provide patients and their families with the information they need to make truly informed decisions about whether to have a surgical procedure, as well as which cardiothoracic surgical program may provide them the greatest likelihood of a successful outcome. This fulfills the ethical principle of patient autonomy, or fully informed decision-making. Robust risk-adjustment is also important for surgeons and hospitals who care for the highest risk patients, whose “raw” or unadjusted results might appear worse because of their complex patient mix, but whose risk-adjusted results may demonstrate excellent performance. Proper risk-adjustment prevents these institutions from being penalized or unfairly characterized as under-performing, which might lead them to avoid potentially

higher risk patients. Our risk calculators facilitate discussions of treatment options and outcomes, and they make surgeons and hospitals more likely, rather than less likely, to care for potentially higher risk patients. As a result, they mitigate rather than exacerbate disparities.

The scientific credibility of our performance measures and their underlying risk models is evidenced by the fact that we voluntarily seek the external validation of the National Quality Forum through its endorsement process, the "gold seal" of approval in healthcare quality measurement. Though NQF measure endorsement is an extremely high bar, STS is proud to have the largest number of NQF-endorsed measures of any healthcare professional society. Further, in 2018, STS was awarded the coveted John Eisenberg Award of the Joint Commission and National Quality Forum for its exemplary, decades-long efforts to improve cardiothoracic surgery outcomes nationally.

We hope that the following comments will be useful and that we can work with you and your colleagues to advance our common goal of eliminating disparities and inequities in health care.

As COVID-19 cases hit record levels and racial injustices continue to plague our country, racial health equity remains an unmet promise in the United States. During the 116th Congress, the Committee on Ways and Means has focused on the vital issue of health equity – setting up a Rural and Underserved Communities Health Task Force; holding hearings on issues such as the disproportionate impact of COVID-19 on communities of color, climate change, and maternal mortality; and releasing the report, Left Out: Barriers to Health Equity for Rural and Underserved Communities.[1] As part of this important work, I also sent letters to seven professional societies and the Centers for Medicare & Medicaid Services inquiring about the issue of racial bias in clinical tools; due to widespread interest in this topic, I subsequently initiated a request for information (RFI) for other stakeholders to share their perspective.

STS is deeply committed to the elimination of racial bias and disparities in healthcare. However, your reference to "…the issue of racial bias in clinical tools" conveys the false premise that inclusion of race in healthcare risk-prediction models is, ipso facto, an indication of racial bias. We disagree with that characterization.

Race variables are included when empirical data show that they improve the scientific accuracy of a specific risk model, and when there is a plausible causal association with an outcome, even when the exact mechanism underlying that association is incompletely understood. This lack of complete mechanistic understanding is also true for many if not most other clinical or demographic risk factors that are statistically significant model predictors. Our goal is to produce the most accurate predictive models, and this benefits all stakeholders, most of all patients (irrespective of race, ethnicity, sex, or gender) but also providers, payers, and regulators interested in assessing and improving quality of care.

Given the work of STS on improving surgical outcomes, I am writing to learn more about work underway at STS to investigate, raise awareness, and change clinical decision support tools – like the Short-Term Risk Calculator (STRC) – that could exacerbate racial inequities in surgical outcomes.

Science has debunked the biological definition of race, but clinical tools like the STRC continue to use race and ethnicity in ways that exacerbate inequities operative morbidity and mortality.

We are aware of no objective evidence that STS risk models use race and ethnicity in ways that "exacerbate racial inequities" in operative morbidity and mortality. The recent *New England Journal of Medicine* article by Vyas and colleagues, "Hidden in Plain Sight—Reconsidering the Use of Race Correction in Clinical Algorithms," is replete with mischaracterizations regarding the development and use of STS risk models. Because of our strenuous, evidence-based objections regarding a preliminary online version of that article, the final print version was partially modified by the authors and NEJM. Unfortunately, other misleading information was retained, including the example they provide of how different risk estimates could ostensibly be used to deny care to Black patients. Frankly, it is quite disappointing that this example passed the peer-review editorial vetting process at NEJM, as it is a classic demonstration of how numbers can be misrepresented to support an author's preferred conclusion. Their example also reflects the authors' inexperience and limited understanding of how risk models are developed and applied in practice; the distinction between absolute and relative numerical differences; the need to determine whether such differences have statistical or practical importance; and the actual range of mortality rates in cardiac surgery.

Specifically, Vyas and colleagues state: "An isolated coronary artery bypass in a low-risk white patient carries an estimated risk of death of 0.492%. Changing the race to 'black[sic]/African American' increases the risk by nearly 20%, to 0.586%. …When used preoperatively to assess risk, these calculations could steer minority patients, deemed to be at higher risk, away from surgery." This example is uninformed and grossly misleading. The absolute difference between these two estimates is 0.00094, and both the Black and White mortality estimates would be considered by any cardiac surgeon as low risk and virtually identical. We cannot conceive of any scenario in which this magnitude difference would ever dissuade a patient or a surgeon away from surgery. Even a 20% relative difference in risk for a much higher risk patient (e.g., 10% versus 12%) would not be considered clinically meaningful from the perspective of "steering" a patient away from cardiac surgery.

As we discuss below, elimination from the risk models of any factors known to be associated, on average, with increased risk would reduce the accuracy of the model and its ability to "protect" both patients and the providers willing to accept high-risk patients. The unintended consequence would be just the opposite of what you are trying to accomplish. Providers would lose trust in the accuracy of the models to correctly characterize high-risk patients, and they might be less willing to accept such patients.

Finally, the comment that "Science has debunked the biological definition of race" is an oversimplification of a highly complex topic as well as being potentially misleading. It is true that traditional racial categories are socially derived and reflect historical continental origins, and that there are more genetic differences within than between racial categories. However, these facts should not be construed to imply that socially-defined racial groups do not differ biologically or genetically, including their risk for certain diseases, better or worse outcomes with certain diseases, and differential

responsiveness to certain medications. Further, experts in population genetics have published numerous large studies showing that genetic clustering consistent with continentally-based racial ancestry persists in the modern era, and that differences in human genetic structure are highly correlated with self-identified racial classification.[1-6] In summary, genetic, environmental, social, political, behavioral, or other non-inherited factors may all contribute, individually, or jointly, to our understanding of racial/ethnic health disparities. These contributions may differ considerably depending on the disease or trait being studied.

As you know, the STRC tool predicts intraoperative[1] mortality and complications for common cardiac surgeries. Clinicians use it to guide decisions on when and how to offer surgery. The effect of the tool is that White patients are considered the baseline or default setting while Black patients are systematically scored as higher risk for death and complications thus lower need for aggressive treatments.

We interpret this statement to imply that the Committee believes the STS risk calculator somehow lowers the perceived need or willingness to offer aggressive treatment in some patients because it assigns them higher risk. If we are correct in this interpretation, then the statement would appear to conflate the issues of ***appropriateness*** and ***risk***. STS risk models have nothing to do with the "need for aggressive treatments," which reflects what is generally referred to as *appropriateness*. Determination of the appropriateness of a procedure for a given patient is based on recommendations from evidence-based guideline documents published by professional societies such as the American Heart Association, the American College of Cardiology, and the Society of Thoracic Surgeons. In cardiothoracic surgery, these guideline recommendations usually consider clinical factors (e.g., the presence of severe angina or shortness of breath) and anatomic or physiologic data (e.g., the degree of blockage in a coronary artery, or the degree of heart valve obstruction or leakage). We are unaware of any guideline recommendations that incorporate race parameters in defining appropriateness criteria for cardiothoracic surgery.

Once the *appropriateness* of a patient for a potential intervention has been confirmed, then their *risk* of undergoing that procedure is estimated using risk calculators, like those developed by STS. Contrary to your statement, cardiovascular specialists know that it is often the highest risk patients who may benefit most from aggressive treatment and, because of this, they are often offered cardiac surgery rather than other non-surgical treatments. The overall risk profile of patients undergoing many cardiac surgical procedures, such as CABG, has been systematically shifting to include more high-risk patients over the years, but because of improved techniques in operative and perioperative care, the results are constantly improving. Cardiac surgeons are quite accustomed to treating high risk patients and generally willing to do so unless the risks are so prohibitive that they clearly outweigh the expected benefits. We are unaware of a scenario where inclusion of race parameters in any of the STS risk models would drive risk estimates to prohibitive levels. From the provider perspective, the willingness of surgeons to provide care to higher risk patients reflects their trust in the ability of STS and other risk models to accurately account for risk across all patient groups when determining surgeon or hospital performance. In fact, studies have shown that hospitals caring for the highest risk patients often have the best risk-adjusted outcomes. [7,8]

[1] The STRC predicts operative mortality. It does not predict intraoperative mortality.

The STS risk models are based on empirical data collected from 90-95% of all patients in the US undergoing cardiothoracic procedures, and these data are analyzed by teams of highly trained statisticians and surgeons. The inclusion of race in STS risk models undoubtedly encompasses numerous factors that, *on average and in aggregate*, impact patient outcomes and which are not fully accounted for by other variables in the models. These include but are not limited to genetic factors; socioeconomic and sociodemographic factors; behavioral or environmental factors; other non-inherited factors; and access to care. Importantly, STS analyses show that the empirical association of race and certain outcomes persists even when Socioeconomic Status (SES) markers such as dual eligible status are simultaneously included in the models. Further, omission of race from some STS models causes a substantial decrease in risk model calibration (i.e., predictive accuracy), especially when applied to Black patients, for whom risk prediction would then be particularly misleading. Absent inclusion of this variable, consent discussions with Black patients would be knowingly inaccurate, which we would regard as unethical practice.

Racial inequities exist in cardiac surgery outcomes. Considering these concerns, inclusion of race in this tool must be reevaluated. Medical professional societies should take a clear stand against the misuse of race and ethnicity in clinical algorithms and issue new guidance to correct this practice.

While STS agrees that "…misuse of race and ethnicity in clinical algorithms" must be avoided, we do not believe that "use" should be assumed to equate with "misuse." We strongly believe that when STS includes race in risk models, it is scientifically appropriate and objectively based on empirical data and rigorous analytic methodologies. In fact, refraining from the use of race in algorithms where clinically and statistically appropriate could be considered negligent.

Professional societies must evaluate, on a model by model basis, the conceptual rationale for the inclusion of race, ethnicity, or socio-demographic status (SDS)/SES factors in specific risk models; the empirical evidence for their inclusion; and the potential for misuse and the mitigation thereof. These models should be frequently re-assessed based on the most current data.

To "issue new guidance to correct this practice" by uniformly eliminating race from all predictive models would in fact have the potential to harm rather than help minority patients. Consider the following example: Based on extensive independent modeling by the STS Research Center and the Duke Clinical Research Institute, using the most recent US data from our clinical registry, elimination of race from some STS risk models would produce predictions that systematically underestimate, on average, the risk of Black patients for certain adverse outcomes, even if socio-demographic factors are also included in the models. Were such changes to be implemented, Black patients would knowingly be given false estimates of their risk during informed consent discussions, an unethical practice. At the same time, providers caring for disproportionately more Black patients would know that the risk of these patients was being systematically and falsely underestimated. With no change in their actual performance, providers' ratios of observed to expected mortality and risk-adjusted mortality rates (two ways of measuring performance) would increase, making it appear that they were under-performing (i.e., that their outcomes are worse than expected). Seeking to avoid reputational harm or financial penalties, such programs might consequently be incentivized to decrease access to Black patients, a phenomenon referred to as risk aversion. This decreased access would harm rather than promote cardiovascular health in vulnerable minority populations, exactly the opposite of what the Committee and STS are striving to achieve.

Leadership from professional societies like STS is a critical part in addressing health inequities and, specifically, ending the inappropriate use of race in the STRC tool.

We share your desire to address health inequities and would welcome the opportunity to be a part of the solution. We agree that "inappropriate" use of race in predictive models should be eliminated, but for all the reasons discussed previously, we believe that our use of this variable in our risk models is data-driven, appropriate, and may in fact be part of the solution rather than a problem.

1. What strategies has STS undertaken to reevaluate the scientific basis for the use of race in STRC calculation?

STS, in conjunction with the Duke Clinical Research Institute, an internationally recognized clinical research organization which assists in the design and implementation of our risk models, has undertaken the following steps to assure that race is properly used in any STS risk models. Many of these considerations antedate the Vyas article in NEJM and your letter, and are part of our continuous efforts to optimize STS risk models and performance measures:

a. STS has familiarized itself with relevant recommendations, pro and con, regarding the inclusion of SES/SDS and race variables in healthcare risk models, including but not limited to documents published by NQF, the National Academy of Medicine, and two reports to Congress by the Assistant Secretary for Planning and Evaluation (ASPE).
b. As noted earlier in this document, STS has had extensive, detailed discussions with international leaders in population genetics. We have also studied numerous publications spanning the spectrum of opinions regarding the association of traditionally-defined racial categories with some genetic markers that may impact outcomes (e.g., renal failure) and responsiveness to medications (e.g., for heart failure).
c. STS risk models used to measure performance and quality of care are dynamic in nature. STS routinely re-calibrates all its risk-models based on new data. If any risk factor, including race, becomes empirically less important in the model (e.g., a smaller coefficient or odds ratio), its reduced impact will be reflected in the next application of that model, or it may be eliminated.
d. The STS Research Center and the Duke Clinical Research Institute have conducted separate extensive studies of our most important risk models to determine the impact of the inclusion of race. The results are fully concordant. These studies included model calibration analyses overall and in racial and SES subpopulations, with and without race variables, and with and without race + dual eligible socio-economic status indicators (to determine if those were accounting for risk that was misattributed to race). These analyses have shown substantial miscalibration (predictive inaccuracy) of certain models when race is omitted, especially in Black subpopulations and even when dual eligible status is included. These studies are ongoing, and race will be eliminated, or its risk model coefficient diminished, when such actions are supported by empirical data.
e. STS has contracted with a major university to *geocode* all entries in its adult cardiac surgery database and is using these geocodes to assign an area deprivation index (ADI) to each patient. This is widely regarded as the best current indicator of SES/SDS and will be included in future risk model development. The effect of including this variable on the empirical association of race and predicted risk will be continuously evaluated.
f. Although we already have a frailty indicator in our Database, it requires additional staff effort to collect and has not been used consistently by participants. We have now formed an STS

working group to develop a frailty indicator based on history, patient-reported functional ability, and labs (e.g., serum albumin, anemia) that will hopefully allow us to collect a frailty assessment on most or all patients. This could then be included in future STS risk models, a "functional status" indicator as advocated by the October 2020 ASPE Report to Congress, which theoretically might account for some of the outcome association currently attributed to race.

g. STS will expand its analyses of outcomes data stratified by race and SES/SDS status and will provide these in feedback reports to STS Database participants, as recommended by most organizations who have provided guidance in this area.[9]

a. How will STS work to support, encourage, and coordinate with other specialty organizations that are also conducting a reevaluation of the misuse of race in clinical algorithms?

As stated previously, we disagree with your use of the phrase "...misuse of race in clinical algorithms", which seems to characterize any and all uses of race in clinical algorithms as "misuse." STS has communicated with other professional specialty organizations regarding the use of race in their predictive models, potential pros and cons, and alternative approaches.

2. What has STS done and what does it plan to do to inform clinicians of the connection between use of race in STRC calculation and racial health inequities in cardiac surgery outcomes?

a. While ending the use of race in the STRC could take some time to implement, what guidance can STS issue quickly to redirect clinical practices and communicate the problem of misuse of race in the STRC to patients?

For the same reasons discussed in our response to the previous question, we are concerned about the underlying premise of this question and are also unclear as to what "clinical practices" you suggest should be redirected. Based on extensive analyses by the STS Research Center and the Duke Clinical Research Institute, using the most current STS Database data, we believe that elimination of race from all STS risk models at this time would be scientifically inaccurate and result in an intentional, unethical misrepresentation of facts to certain patient populations, most notably Black patients.

3. What interventions could STS develop to ensure improved access to cardiac surgery for patients who have not received it because of use of race in the STRC?

a. What role could the federal government play in support of this kind of initiative, if any?

While we have no evidence, either empirical or anecdotal, that any patient has not received cardiac surgery care "because of use of race in the STRC", we would welcome the opportunity to work with you to investigate this concern. In fact, we would appreciate the opportunity to engage in more expansive discussions with policy-makers about how to implement national policies to eliminate all health disparities including demographic, geographic, and other types of differences in access to care.

b. What specific racial health equity metrics and outcomes will STS track and work to improve? Please provide details, including the timeframe.

STS will continue and expand our monitoring of patient outcomes stratified by subpopulation characteristics, including race. This will allow STS and its members to track outcomes in specific patient populations including racial groups. However, our registry only includes patients who have undergone surgery. Neither STS nor its members have access to data regarding patients not referred to surgeons, declined by surgeons, or who themselves declined to accept surgery. Thus, with data available in the STS Database, we cannot address another important manifestation of racial inequity -- access to care.

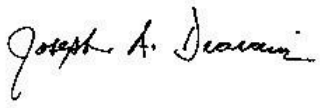
4. Black, Indigenous, and Latinx scholars have a leading and vital perspective on these issues and the proposed solutions, despite being underrepresented in medicine. How is STS ensuring racial diversity in the discussion and strategy development relating to health equity?

STS is committed to advancing diversity, equity, and inclusion in our organization and within the health care system. We recognize that unacceptable disparities exist in health care and are keenly aware of the importance of engaging diverse perspectives. Our immediate STS past-president is a distinguished Black cardiac surgeon, and he continues to serve on the STS Board of Directors and Executive Committee. In 2019, STS implemented a Workforce on Diversity, Equity and Inclusion, chaired by a prominent Black thoracic surgeon. This STS Leadership Body is part of our governance structure and focuses on developing tangible resources to help address health disparities within the cardiothoracic surgery clinical, scientific, education, and advocacy arenas.

STS established the "Vivien Thomas Lecture" at its 2020 annual meeting, honoring the Black surgical technician at Johns Hopkins who contributed immeasurably to the early development of congenital cardiac surgery. A generous lectureship fund has been developed to maintain this as a central plenary session during the STS Annual Meeting for many years to come.

In conclusion, by pursuing an objective, data-driven approach which is also sensitive to the health policy implications of various modeling approaches, we can work together to advance our common goal of promoting healthcare equity, while at the same time avoiding reflexive, wholesale changes that might paradoxically harm both patients and providers. We look forward to continuing a conversation with you on this topic of critical importance to our healthcare system and our society.

Sincerely,



Joseph A. Dearani, MD
President

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