FACT VERSUS FICTION:

CLINICAL DECISION SUPPORT TOOLS AND THE (MIS)USE OF RACE

Majority Staff Report

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THE WAYS AND MEANS COMMITTEE'S FOCUS ON RACIAL EQUITY

During the 116th Congress, the Committee on Ways and Means explored the root causes of health and economic disparities, inequitable outcomes in maternal mortality, climate change, gun violence, and the disproportionate impact of COVID-19 on communities of color. A Committee Majority Staff report, *Left Out: Barriers to Health Equity for Rural and Underserved Communities,* highlighted ways that implicit bias and racism can undercut efforts to achieve health equity and racial justice.

In the 117th Congress, the Committee continues to expand upon this work, as outlined in the Committee Majority Staff report, *Something Must Change: Inequities in U.S. Policy and Society*, and accompanying legislative framework, *A Bold Vision for a Legislative Path Toward Health and Economic Equity.*

In March 2021, Chairman Richard E. Neal Announced the formation of the Racial Equity Initiative (REI), co-led by Reps. Terri A. Sewell (D-AL), Jimmy Gomez (D-CA), and Steven Horsford (D-NV). The REI is focused on helping the Ways and Means Committee understand, reconcile, and remedy pervasive racial inequalities in health and economics through policymaking that supports more equitable outcomes and inclusive opportunities for all Americans. In July 2021, the REI co-chairs issued a *set of equity-informed recommendations related to infrastructure and budget reconciliation priorities.*

In this report, we build upon the Committee's work on racial health equity by examining the misuse of race and ethnicity in tools and algorithms used to support clinical decision-making.

A NOTE ON TERMINOLOGY

The terminology used to describe marginalized groups in this report is intended to be as inclusive as possible while recognizing there are differences in how individuals who are members of these groups identify. This report uses consistent terms throughout to help ensure clarity. However, we note that some terms may not reflect the preferences of all individuals these references may capture.

EXECUTIVE SUMMARY

Since the early 1900s, scholars – primarily from communities of color – have critiqued the way racism has influenced clinical science and medicine. By its nature, science is objective and intended to produce empirical, replicable, and unbiased results. Yet, the legacy of anti-Black views used to justify slavery continue to influence and skew many of the methods used in clinical science and medicine today. These racist views have historically influenced the lack of representation among people of color within these fields, which has helped fuel skepticism of science, medical professionals, and the health system among many racial and ethnic groups. Racial bias has also resulted in the endorsement of benchmarks, predispositions, and prognoses that center the health experiences of White populations as the norm for all patients. In some instances, this approach includes adjusting a metric based on the variation between the patient and the established norm – a practice known as "race correction."

Figure 1. Example of CDSTs

CLINICAL TOOL	CLINICAL DECISION SUPPORT IMPACT
Get with the Guidelines: Heart Failure	Risk for in-hospital death from heart failure
Vaginal Birth After Cesarean (VBAC)	Rate of complications when attempting vaginal birth after cesarean
Estimated glomerular filtration rate (eGFR)	Level of kidney function
Osteoporosis Risk SCORE and Fracture Risk Assessment Tool (FRAX)	Risk for fracture
Short-term surgical risk calculation (STR)	Risk for death and complications

As advances in technology continue to disrupt traditional health care delivery, it is important to ensure the lessons of the past inform the future of our nation's health. This means ensuring that new technologies embrace maximum inclusivity by ensuring the clinical algorithms that power them properly use race.

Clinical support tools (CDSTs) can help address racial health disparities, advance health equity, modernize health systems and care delivery, and improve quality of care. CDSTs play an important role in health care planning and delivery, offering clinicians timely information within the context of individual patient conditions. However, their potential to advance equity while addressing disparities is complicated by the reality that the methods and assumptions used in the algorithms at the core of CDSTs may themselves import biases that are detrimental to patients of color.

The potential for racial bias in CDSTs was recently highlighted in a 2020 study published in *The New England Journal of Medicine* in which researchers found that while CDSTs can be helpful in streamlining complex health information and assisting clinicians in diagnosing conditions and recommending treatment, they can also incorporate racial biases that have detrimental effects on patients of color. Notably, race correction in CDSTs was shown to be harmful for patients in a range of scenarios and conditions, from childbirth to cancer.[1] Despite their usefulness, the tools themselves can perpetuate health inequities because of how they

[1] Vyas DA, et al., Hidden in Plain Sight – Reconsidering the Use of Race Correction in Clinical Algorithms, 383 New Eng. J. of Medicine 874—882 (2020).

consider race and ethnicity, too often in ways that amplify racial disparities, reduce the rigor of personalized diagnostics, and result in fewer treatment options for people of color.[2, 3, 4, 5, 6]

The implications of the misuse of race in clinical algorithms is profound for medical education, clinical education, research, and, ultimately, patient outcomes. Researchers have demonstrated that false beliefs in a biological basis for race negatively impact clinical care through racial biases that influence everything from pain assessment to treatment.[7] Past research has also highlighted that these biases among medical professionals and within health systems have contributed to disparities in health care access and utilization among Asian Americans, as well as utilization of mental and physical health services among Latino Americans.[8,9,10] Furthermore, the presence of higher chronic disease rates among people of color, suggests systemic health disparities that negatively impact all non-White populations, including Indigenous Americans for whom diabetes and cardiovascular disease are among the leading causes of death.[11]

> *"The truth is, that medicine, professedly founded on observation, is as sensitive to outside influences, political, religious, philosophical, imaginative as is the barometer to the changes of atmospheric density."*
>
> — Oliver Wendell Holmes, Sr.
> Currents and Counter-currents in Medical Science, 1860

In response to the concerns raised by the findings in the 2020 study, Ways and Means Committee Chairman Richard E. Neal (D-MA) sent a series of letters in September 2020 to professional medical societies that have created or endorsed the use of CDSTs..[12] Following the

[2] Obermeyer Z, et al., Dissecting Racial Bias in an Algorithm Used to Manage the Health of Populations, 366:6464 Science 447—453 (2019).
[3] Kolata G, Many Medical Decision Tools Disadvantage Black Patients, N.Y. Times (June 17, 2020), https://www.nytimes.com/2020/06/17/health/many-medical-decision-tools-disadvantage-black-patients.html.
[4] A Race to The Bottom: How AI Encodes Racial Discrimination within Medicine, Medical Technology (Sept. 2020), https://medical-technology.nridigital.com/medical_technology_sep20/ai_racial_discrimination_medicine.
[5] Schmidt IM, et al., Separate and Unequal: Race-Based Algorithms and Implications for Nephrology, 32:3 J. Am. Society of Nephrology 529—533 (2021).
[6] Braun L, et al., Racialized Algorithms for Kidney Function: Erasing Social Experience, 268 Social Science & Medicine (2021).
[7] Hoffman KM, et al., Racial Bias in Pain Assessment and Treatment Recommendations, and False Beliefs About Biological Differences Between Blacks and Whites, 113:16 PNAS 4296—4301 (2016).
[8] Ye J, et al., Health Care Access and Utilization Among Us-Born and Foreign-Born Asian Americans, 14 J. of immigrant & Minority Health 731—737 (2012).
[9] Chang CW, et al., Factors Affecting Mental Health Service Utilization Among Latino Americans with Mental Health Issues, 27:6 J. of Mental Health 552—559 (2018).
[10] Betancourt JR, Barriers to Health Promotion and Disease Prevention in the Latino Population, 6:3 Clinical Cornerstone 16—29 (2004).
[11] Sarche M, et al., Poverty and Health Disparities for American Indian and Alaska Native Children: Current Knowledge and Future Prospects, 1136 Annals N.Y. Academy of Sciences 126—136 (2008) and Disparities, Indian Health Service (Oct. 2019), https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/factsheets/Disparities.pdf.
[12] In a Series of Letters, Neal Calls on Professional Medical Societies to Push Racial Health Equity Agenda Forward, Committee on Ways & Means (Sept. 3, 2020), https://waysandmeans.house.gov/media-center/press-releases/series-letters-neal-calls-professional-medical-societies-push-racial.

first set of letters, the Chairman issued a Request for Information (RFI) to solicit input and recommendations from a broader group of stakeholders with interest in this matter.[13]

Generally, responses to the Chairman's letters and the RFI reflect tacit acknowledgement of the unacceptable nature of the findings that certain CDSTs produce avoidable differences in outcomes for patients of color – with about one-third of organization and professional society respondents saying they are not planning to reevaluate the use of race and ethnicity in clinical algorithms. Respondents uniformly raised the absence of a central hub of accountability as a barrier to addressing the complex issues across scientific and medical professions. Similarly, many responses emphasized the role of bias in CDST development and care delivery, suggesting the solution to these issues lies upstream (e.g., at the level of health technology research and development and through clinician education). Most responses noted that addressing health inequities will require acknowledging the structural inequities present in clinical science and medicine and a willingness to be accountable for their impact on persistently disparate health outcomes. Finally, respondents recommended leadership from the largest and most influential organizations (e.g., the Centers for Medicare & Medicaid Services) to assemble stakeholders to develop standards, guidance, and best practices for using race in CDSTs.

This report, *Fact versus Fiction: Clinical Decision Support Tools and the (Mis)Use of Race,* recounts the conflicted history among science, medicine, and race; describes the evolution of tools designed to improve efficiency and quality of care; highlights consistent and divergent themes within the universe of responses to the Chairman's outreach; and discusses the challenges of achieving consensus within scientific and clinical professions. We conclude that while data on race and ethnicity are key to showing how socioeconomic factors, including racism, cause disparities in outcomes, misuse of that data further entrenches baseless and dangerous racial distinctions.

As society recovers from the height of the COVID-19 pandemic and looks to a better and healthier future for all Americans, our efforts must begin with a willingness to be accountable, take an honest and faithful account of our history, and make a national commitment to avoid the pitfalls of systemic inequities that have held us back as a nation for far too long. The Committee on Ways and Means remains prepared to support those efforts and to develop mechanisms to ensure medical organizations are accountable for improving and ultimately eliminating racial health inequities.

[13] Ways and Means Committee Issues Request for Information on the Misuse of Race Within Clinical Care, Committee on Ways & Means (Sept. 17, 2020), https://waysandmeans.house.gov/media-center/press-releases/ways-and-means-committee-issues-request-information-misuse-race-within.

INTRODUCTION

Clinical decision support tools (CDSTs) help providers manage ever-expanding amounts of medical research and information while integrating data to assist them in quickly assessing patients, predicting diagnoses or outcomes, and determining treatment options.[14] CDSTs may vary widely in their scope, usage, utility, effectiveness, and evidence-base, but they are pervasive across clinical settings and are used in care delivery under an array of scenarios (e.g., kidney and lung function or risks associated with various birthing methods).[15] Clinical algorithms are among the most sophisticated of CDSTs, designed for enhanced precision in patient care decisions and outcome predictions to achieve the best possible patient outcomes.[16]

As the United States (U.S.) grapples with the disparate impacts of the coronavirus (COVID-19) and an overdue national reckoning with race, the complicated history between the scientific community and race has also taken on new urgency, including the ways racism can influence the structures and systems within society.[17] A June 2020 study, published in *The New England Journal of Medicine* (NEJM), showed that adjustment for race in CDSTs and clinical algorithms is harmful for a range of conditions from childbirth to cancer.[18] Clinical algorithms tend to incorporate vast amounts of inferential intelligence data from an array of sources ("Big Data"), including the social constructs and biases that are embedded in those data.[19] This structural vulnerability means that despite their utility, many CDSTs themselves introduce an element of health inequity because they consider race and ethnicity in ways that exacerbate existing racial disparities, reduce the rigor of personalized diagnostics, and result in fewer treatment options for people of color.[20, 21, 22, 23, 24]

> *"To achieve meaningful social justice, it is important to uncover the invisible processes by which race and racism operate in societies, including how they have burrowed their way into the popular psyche, the scientific imagination – and, crucially, have been translated, albeit unwittingly, into empirical medical 'facts' like race correction."*
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> — Braun L, et al., Racialized Algorithms for Kidney Function: Erasing Social Experience, 268 Social Science & Medicine (2021).

[14] CDSTs are also referred to as clinical decision support (CDS), CDS systems (CDSSs), and algorithms in the literature; for the purposes of clarity in this report, we refer primarily to CDSTs as an umbrella term.

[15] Vyas DA, et al., supra note 1. Lytle KS, Clinical Decision Support for Nurses: A Fall Risk and Prevention Example, 33:12 CIN: Computers, Informatics, Nursing 530—537 (2015). Feldstein D et al.,Implementation of Nurse Driven Clinical Decision Support to Improve Primary Care Management of Sore Throat, Univ. Wisconsin-Madison School of Medicine & Public Health (2019), https://www.fammed.wisc.edu/files/webfm-uploads/documents/research/wren/2019/57-gim_feldstein_nurse-clinical-decision-support-sore-throat.pdf.

[16] Zuzelo PR, Overcorrection of Clinical Algorithms: Intended Holism Gone Awry?, 34:6 Holistic Nursing Practice 380—382 (2020).

[17] Matthew DB, Just Medicine: A Cure for Racial Inequality in American Health Care (NYU Press 2015).

[18] Vyas DA, et al., supra note 1.

[19] Braun L, et al., supra note 6.

[20] Obermeyer Z, et al., supra note 2.

[21] Kolata G, supra note 3.

[22] A Race to The Bottom, supra note 4.

[23] Schmidt IM, et al., supra note 5.

[24] Braun L, et al., supra note 6

Figure 2 depicts one standard CDST, predicting the chance of a successful Vaginal Birth After Caesarean (VBAC), as applied to four hypothetical patients of comparable height, weight, and age. As the figure shows, *purely based on race and ethnicity*, the CDST automatically gives these four hypothetical women different predictions of a successful VBAC.

Figure 2. Hypothetical Patients Presenting for Vaginal Birth After Cesarean (VBAC) and Resulting Score from CDST

Maternal Age:			24 years
Height (range 4ft 6in to 6ft 10 in):			5ft 3in
Weight (range 80-310 lb):			130 lb
Body Mass Index (BMI, range 15-75):			23 kg/m2
Previous vaginal delivery:			No
Any vaginal delivery since last cesarean:			No
Indication for prior cesarean of arrest of dilation or descent:			No
RESULTS: Predicted chance of successful vaginal birth after cesarean (95% confidence interval)			
White Race/Ethnicity	Black Race/Ethnicity	Latino Race/Ethnicity	Black & Latino Race/Ethnicity
80.9%	68.4%	68.2%	52.3%
[78.9%, 82.7%]	[65.3%, 71.3%]	[65.0%, 71.2%]	[47.3%, 57.3%]

Experts on the intersections between CDSTs and race and ethnicity recommend promoting structural competency within the health care sector, premised on a holistic understanding of society, alongside broader efforts to improve health equity.[25, 26] Accordingly, in September 2020, Committee on Ways and Means Chairman Richard E. Neal (D-MA) called on the leaders of several professional societies and other stakeholder organizations to partner with the Committee in addressing longstanding racial disparities in health care outcomes as they relate to CDSTs.[27] Chairman Neal asked respondents for their perspectives on a series of questions related to their medical expertise. For more information on the solicitation, please see Appendix A and B.

This report offers background on the evolution of CDSTs and how the misuse of race as a variable in the social determinants of health outcomes became pervasive in Western medicine, analyzes perspectives of professional societies and stakeholders who responded to the Committee's Request for Information (RFI) on issues relating to CDSTs, and discusses paths forward.

[25] Metzl JM, et al., Structural Competency and Psychiatry,75:2 JAMA Psychiatry 115—16 (2018).
[26] Metzl JM, et al., Responding to the COVID-19 Pandemic: The Need for a Structurally Competent Health Care System 324:3 JAMA 231–232 (2020).
[27] In a Series of Letters, Neal Calls on Professional Medical Societies to Push Racial Health Equity Agenda Forward, supra note 12.

BACKGROUND

Why should we consider race, ethnicity, and technology in health care delivery?

"Race" is "a *socially constructed* concept used to group people, based on skin color and other apparent physical differences," and "ethnicity" refers to a variety of sociocultural relationships and practices where alignment is fluid and can change over time.[28, 29, 30] As recently as 2018, the American Society of Human Genetics issued a statement: "[G]enetics demonstrates that humans cannot be divided into biologically distinct subcategories," as analyses of the human genome show more differences within racial groups than there are among racial groups.[31, 32] Advancements in genetics have unlocked the mutations responsible for conditions that tend to affect one racial group most of the time (e.g., sickle cell anemia or cystic fibrosis), but the diseases themselves are indifferent to the race of the individual.[33] Thus, it is well established that neither race nor ethnicity are predicates to or predictors of optimal body function, and neither is synonymous with one's individual, or a group's collective, health.

The concepts of bias or prejudice are as old as human civilization itself. However, the idea of a racial hierarchy gained firm footing in the Americas during the colonial era. When the U.S. ended the institution of chattel slavery and the Union prevailed in the Civil War, newly freed Black people embarked on the long journey of accessing freedoms the Constitution promised to citizens. As the emancipated began to establish themselves in education, work, and society, they did so under two dominant schools of thought. The first – that subpar treatment of Black people was

> ### KEY TERMS
>
> **Race** – a socially and politically constructed way of grouping people, implying common ancestry based on physical characteristics alone.
>
> **Racism** – a system of structuring opportunity and assigning value based on how one looks, which unfairly advantages some and disadvantages others.
>
> **Ethnicity** – a variety of sociocultural relationships and practices that can be fluid and change over time.
>
> **Inequity** – unfair or unjust distributions of resources across social, economic, environmental, and health care systems.
>
> **Algorithm** – step-by-step procedures used for calculation, data processing, and automated reasoning.
>
> **Clinical decision support tools** – the integration of data and research to help clinicians assess patients' health, predict diagnoses or outcomes, and determine options for diagnostic tests and treatment.
>
> **Big Data** – data containing greater variety and volume, with increasing speed.
>
> **Structural competency** – recognition of ways institutions, neighborhood conditions, market forces, public policies, and health care delivery systems shape symptoms and diseases, and mobilization of resources for correction of inequalities as they manifest in the health sector and beyond.

[28] Jones CP, Levels of Racism: A Theoretic Framework and a Gardener's Tale, 90:8 Am. J. Public Health 1212—1215 (2000).

[29] Sankar P, MEDLINE Definitions of Race and Ethnicity and Their Application to Genetic Research, 34:2 Nature Genetics (2003).

[30] Standards for the Classification of Federal Data on Race and Ethnicity, 60 Fed. Reg. 166, 44675 (Aug. 28, 1995).

[31] ASHG Denounces Attempts to Link Genetics and Racial Supremacy. 103 Am. J. Human Genetics 636 (2018).

[32] AAPA Statement on Race & Racism, Am. Assoc. Biological Anthropologists (Mar. 27, 2019), https://physanth.org/about/position-statements/aapa-statement-race-and-racism-2019/.

[33] Melilo G, Study Finds Funding Disparities Between Sickle Cell Disease, Cystic Fibrosis, AJMC (Mar. 30, 2020), https://www.ajmc.com/view/study-finds-funding-disparities-between-sickle-cell-disease-cystic-fibrosis.

justified because they were inherently inferior – formed the basis for systemic racism to become embedded within the fields of science and medicine. For example, from 1845 to 1849, Dr. J. Marion Sims, the "father of gynecology," experimented on enslaved Black women without anesthesia or consent, citing the unfounded belief that Black people experienced less pain than White people. [34] Nearly 200 years later, studies show some medical students and physicians still subscribe to this fallacy.[35] The second prevailing belief – that emancipated Black people had lesser intelligence when compared to their White counterparts – was also steeped in racism and has since had far-reaching implications for all racial and ethnic groups.

The findings published in the *NEJM* indicate that even today, race continues to be misinterpreted or misused in the delivery of health care services through CDSTs, resulting in worse outcomes for people of color. These findings echo concerns about the tendency of "Big Data" and data analytics to replicate or amplify human biases.[36] As discussed further below, Big Data is making marginalized or vulnerable populations more susceptible to incorrect inferences, whether mislabeling pictures of Black people as gorillas, linking profiles associated with ethnic-sounding names with arrest records, allowing advertisers to exclude members of "ethnic affinity groups," or inferring an association between a networking app for homosexual men with one that tracks sex offenders.[37] CDSTs that rely on Big Data to influence clinical care are not immune from layers of bias or discriminatory practices that can pose clear harm for patients, and when unchecked, these inferences can be deadly.[38, 39]

What are clinical decision support tools?

CDSTs consist of a variety of resources that assist clinicians by offering timely information on assessment, diagnosis, and treatment for specific conditions to help inform patient care. They range from basic tools – clinical guidelines, such as clinical order sets for certain types of conditions and computerized prompts for clinicians, support staff, and patients – to more sophisticated tools like clinical algorithms.[40] Clinical algorithms, a subset of CDSTs, aggregate research, large amounts of data, and statistical models to guide clinical assessment, risk prediction, and decision-making.[41, 42] Algorithms serving as CDSTs are designed for

[34] Ojanuga D, The Medical Ethics of the 'Father of Gynaecology', Dr J Marion Sims, 19:1 J. Med. Ethics 28-31 (1993).

[35] Sabin JA, How we Fail Black Patients in Pain, Assoc. AM. Med. Colleges (Jan. 6, 2020), https://www.aamc.org/news-insights/how-we-fail-black-patients-pain.

[36] Lee NT, et al., Algorithmic Bias Detection and Mitigation: Best Practices and Policies to Reduce Consumer Harms, Brookings Inst. (May 22, 2019) https://www.brookings.edu/research/algorithmic-bias-detection-and-mitigation-best-practices-and-policies-to-reduce-consumer-harms/.

[37] Lee NT, Detecting Racial Bias in Algorithms and Machine Learning, 16:3 J. Information, Communication & Ethics in Society 252—260 (2018).

[38] Metzl JM, et al., supra note 26.

[39] The DECID-AI Steering Group, DECIDE-AI: New Reporting Guidelines to Bridge the Development-to-Implementation Gap in Clinical Artificial Intelligence, 27:2 Nature Medicine 186–187 (2021).

[40] Clinical Decision Support, Agency for Health Research & Quality (June 2019), https://www.ahrq.gov/cpi/about/otherwebsites/clinical-decision-support/index.html.

[41] Vyas DA, et al, supra note 1.

[42] Clinical algorithms are connected to but may be distinct from algorithms that use artificial intelligence to input variables and predict outcomes. Many health systems have population health departments that create their own clinical algorithms using patient data from within their health systems to predict various outcomes, but many of these algorithms are proprietary, not publicly released, and are created by developers sometimes without input from clinicians or patients.

maximum relevance, ranging from the most common conditions to customized patient treatment options.[43]

CDSTs can be standalone or integrated into health technology systems, active or passive, and classified as knowledge-based or non-knowledge-based.[44, 45, 46, 47] Knowledge-based tools rely on artificial intelligence (AI) data analysis and conditional rules (i.e., IF-THEN statements) that are developed based on literature, practice, and patient-directed evidence.[48] Similar to knowledge-based systems, non-knowledge-based systems use existing data sources; however, non-knowledge-based CDSTs use AI, machine learning, and statistical pattern recognition in lieu of conditional rules that rely only on existing evidence-bases. Non-knowledge-based CDSTs use probability-based models that leverage data from similar patients' conditions and data mining to inform the best plan of care for a given patient.[49, 50] Knowledge-based CDSTs are more common than non-knowledge based CDSTs, and future knowledge-based CDSTs are less likely to rely solely on unanimous expert opinions (e.g., clinical guidelines.[51]

How have CDSTs evolved over time?

CDSTs have evolved over the last 60 years from siloed systems relying on manual input to more standardized web-based interfaces that communicate across systems.[52] Figure 3 provides a graphical overview of the four distinct phases of development. For a more thorough overview of this history, see Appendix C.

[43] Sittig, DF et al., Implementation of a Computerized Patient Advice System Using the HELP Clinical Information System, 22:5 Computers & Biomedical Research 474–87 (1989).

[44] Dinevski D, et al., Clinical Decision Support Systems, Telemedicine Techniques & Applications (2011).

[45] Middleton B, et al., Clinical Decision Support: a 25 Year Retrospective and a 25 Year Vision, 1:1 Yearbook Med. Informatics S103-16 (2016).

[46] Do Passive Choice or Active Choice Interventions in the EHR Improve Statin Prescribing?, Am. Coll. Cardiology (Oct. 9, 2020), https://www.acc.org/latest-in-cardiology/articles/2020/10/09/16/51/do-passive-choice-or-active-choice-interventions-in-the-ehr-improve-statin-prescribing.

[47] Hajioff S, Computerized Decision Support Systems: An Overview, Health Informatics J. 23—28 (1998).

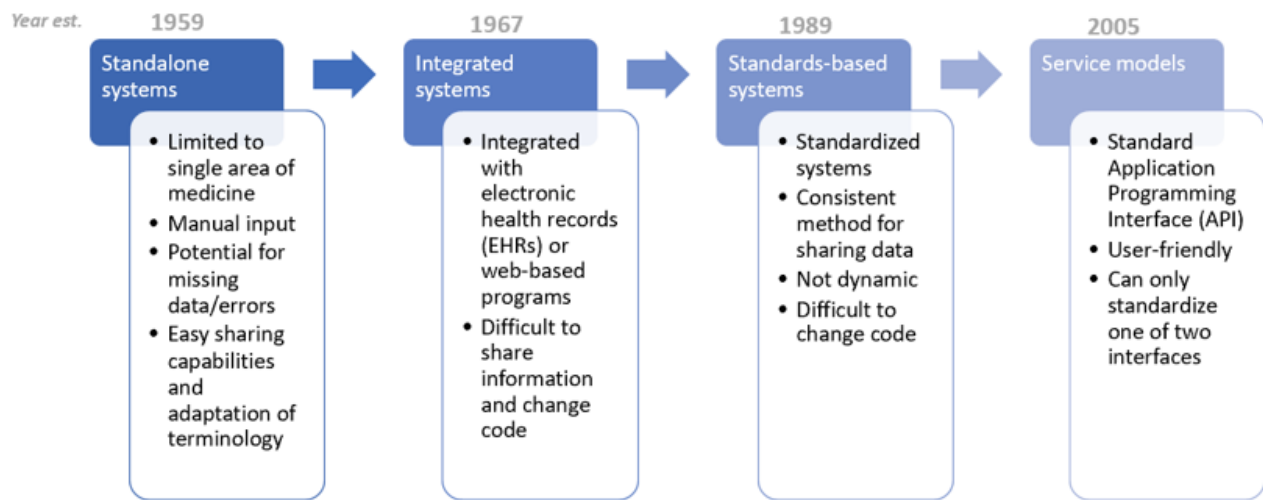[48] Middleton B, et al., supra note 46.

[49] "Data mining" is the practice of harvesting large swaths of data from multiple sources and analyzing trends, outliers, and correlations contained in the data mine.

[50] Dinevski D, et al., supra note 45.

[51] Middleton B, et al., supra note 46.

[52] Id.

Figure 3. Phases of CDST Development

Year est.

1959

Standalone systems
- Limited to single area of medicine
- Manual input
- Potential for missing data/errors
- Easy sharing capabilities and adaptation of terminology

1967

Integrated systems
- Integrated with electronic health records (EHRs) or web-based programs
- Difficult to share information and change code

1989

Standards-based systems
- Standardized systems
- Consistent method for sharing data
- Not dynamic
- Difficult to change code

2005

Service models
- Standard Application Programming Interface (API)
- User-friendly
- Can only standardize one of two interfaces

Source: Middleton B, et al., *Clinical Decision Support: a 25 Year Retrospective and a 25 Year Vision*, 1:1 YEARBOOK MED. INFORMATICS S103-16 (2016).

Why are CDSTs important and how are they used in care planning and delivery?

Over the last six decades, CDSTs have become integral to health care delivery, ushering an era of medicine reliant on some form of technologic assistance. CDSTs help clinicians efficiently and effectively integrate patient data and evidence-based medical information into their decision-making processes. Research shows significant benefits to utilizing CDSTs: improved patient safety (e.g., reduced medication errors), improved care quality (e.g., increased use of latest clinical guidelines), and improved efficiency of health care (e.g., reduction in test duplication, decreased adverse events).[53]

In 2009, Congress expanded opportunities for clinicians to use CDSTs with the passage of the Health Information Technology for Economic and Clinical Health (HITECH) Act.[54] The HITECH Act provided support for and opened the path to dedicate financial resources to support clinicians and hospitals in adopting and meaningfully using integrated technologies, such as CDSTs and electronic health records (EHRs). As a result, by 2013, approximately 41 percent of U.S. hospitals with an EHR system utilized CDSTs and 40.2 percent had advanced CDST capability.[55]

Today, CDSTs are pervasive across the health care sector, with an estimated 74 percent of health care provider organizations using them in some form – with effective results.[56] For example, a hospital in Alabama decreased sepsis mortality by 53 percent through uptake of a

[53] Dinevski D, et al., supra note 45.
[54] American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, Title XIII §13101.
[55] Sutton RT, et al., An overview of clinical decision support systems: benefits, risks, and strategies for success, NPJ Digital Medicine 17 (2020).
[56] Siwicki B, New Study Identifies Top 11 Clinical Decision Support Vendors, Healthcare IT News (Oct. 9, 2018), https://www.healthcareitnews.com/news/new-study-identifies-top-11-clinical-decision-support-vendors.

computerized surveillance algorithm.[57] Harding University in Arkansas found the combination of CDST systems and genetic testing data had potential to reduce hospital readmissions and emergency department visits by 52 percent and 42 percent, respectively.[58] A Department of Veterans Affairs site in Indiana programmed CDSTs to support the reduction of unnecessary lab utilization and found it decreased the total test volume by over 11 percent a year without impacting quality of care.[59]

Though clinicians are the most common users of CDSTs, clinical support staff and patients rely on them as well. CDSTs often include alerts and reminders for things like scheduling the next physician visit, updating personal information, flagging increased fall risks, or assessing risk for strep throat (see Figure 4).[60] Where the fall risk assessment CDST relies on a standard protocol and rule-based output, the strep throat CDST functions as a calculator that determines the risk of strep throat by calculating the patient's risk score (0=no risk to 4=high risk) based on four questions. A study investigating the impact of using the risk calculator for strep throat found several themes: Nurses reported reduced numbers of office visits and unnecessary swabbing (e.g., standard lab strep test), better patient education and health literacy (e.g., rationale for not swabbing), and confidence in their assessments. They also reported reduced costs associated with provider visits and improved patient satisfaction.[61]

Figure 4. Clinical Decision Support Calculator

CDSTs in Action
Strep Pharyngitis Risk Scoring Tool

History of Fever?	1 = Yes	0 = No
Cough?	0 = Yes	1 = No
Tonsillar Exudates?	1 = Yes	0 = No
Tender Anterior Cervical Nodes?	1 = Yes	0 = No
Strep Pharyngitis Risk Score (out of 4)	3	
Approximate Risk of Strep	Intermediate (10-19%)	

Opportunities for innovation using CDSTs abound, yet the variability in sophistication of these tools, high cost of adoption, steep learning curves, and swift evolution of technologies all present challenges to ubiquitous and equitable uptake.

How are clinical algorithms distinct among CDSTs, and how do they connect to racial health inequities?

Today, clinical algorithms represent some of the most sophisticated CDSTs. These algorithms are often designed for personalization and enhanced precision in patient care

[57] Manaktala S, et al., Evaluating the Impact of a Computerized Surveillance Algorithm and Decision Support System on Sepsis Mortality, 24:1 J. Am. Medical Informatics Assoc. 88—95 (2016).
[58] Elliot LS, et al., Clinical Impact of Pharmacogenetic Profiling with a Clinical Decision Support Tool in Polypharmacy Home Health Patients: A Prospective Pilot Randomized Controlled Trial, PLOS ONE (2017).
[59] Konger RL, et al., Reduction in Unnecessary Clinical Laboratory Testing Through Utilization Management at a US Government Veterans Affairs Hospital, 145:3 Am. J Clinical Pathology 355—364 (2016).
[60] Lytle KS, supra note 16.
[61] Feldstein D, et al., supra note 16.

decisions to achieve the best possible patient outcomes.[62] The novelty of CDSTs that use clinical algorithms hinges on the way Big Data factors into function and output of the tool. Since the technology sector first enticed the health care sector by leveraging and maximizing its possession of Big Data, more sophisticated CDSTs have emerged to both fanfare and scrutiny.[63, 64]

> *"Whereas in a previous era, the intention to deepen racial inequities was more explicit, today coded inequity is perpetuated precisely because those who design and adopt such tools are not thinking carefully about systemic racism."*
>
> — Benjamin R, Assessing Risk, Automating Racism, 366:6464 Science 421—22 (2019).

Big Data is an increasingly massive amount of quickly evolving data that is difficult to process using traditional data processing applications because of its complexity.[65] The core characteristics of Big Data are known as the "8 Vs" – volume, variety, velocity, veracity, variability, visualization, volatility, and value.[66]

On the one hand, these tools allow clinicians to quickly and comprehensively assess capacity or condition and provide individualized risk assessments to more effectively guide clinical decisions for an array of scenarios.[67] On the other, the growing reliance on Big Data – the collection of information in real-time across various websites, apps, and other online interactions and repurposing of the data for various uses – presents concerns about how CDSTs incorporate knowledge gleaned from various digital platforms.[68]

While CDSTs have vastly improved medicine, they also remain vulnerable to implicit and explicit biases inherent to Big Data. The collection of these data support laudable goals, such as tracking differences in health indicators and outcomes across races, better targeting interventions, and rectifying deeply engrained inequities. In practice, however, systematic inefficiencies and hardcoded biases can still produce inequities in how the health sector applies information gleaned from Big Data. In the case of CDSTs, there is significant potential for the more advanced tools to address racial inequities if care is taken to acknowledge the underlying data's susceptibility to bias and proactively "clean" the data.[69]

Still, some scholars continue to question the extent to which some CDSTs have been developed in ways that continue to perpetuate racial health disparities. For example, historical evidence suggests that eugenicists Francis Galton, Karl Pearson, and Ronald Fisher created some of the statistical methods included in the design of CDSTs. These men devoted themselves to

[62] Zuzelo PR, supra note 17.
[63] Drees J, 15 Ways Silicon Valley Uses Data for Healthcare: Report, Becker's Health IT (Jan 22, 2020), https://www.beckershospitalreview.com/data-analytics/15-ways-silicon-valley-uses-data-for-healthcare-report.html.
[64] Vyas DA, et al., supra note 1; Lytle KS, supra note 16; Feldstein D, et al., supra note 16.
[65] Mukherjee N, et al., Big Data in eHealthcare: Challenges and Perspectives (CRC Press 2019).
[66] Id.
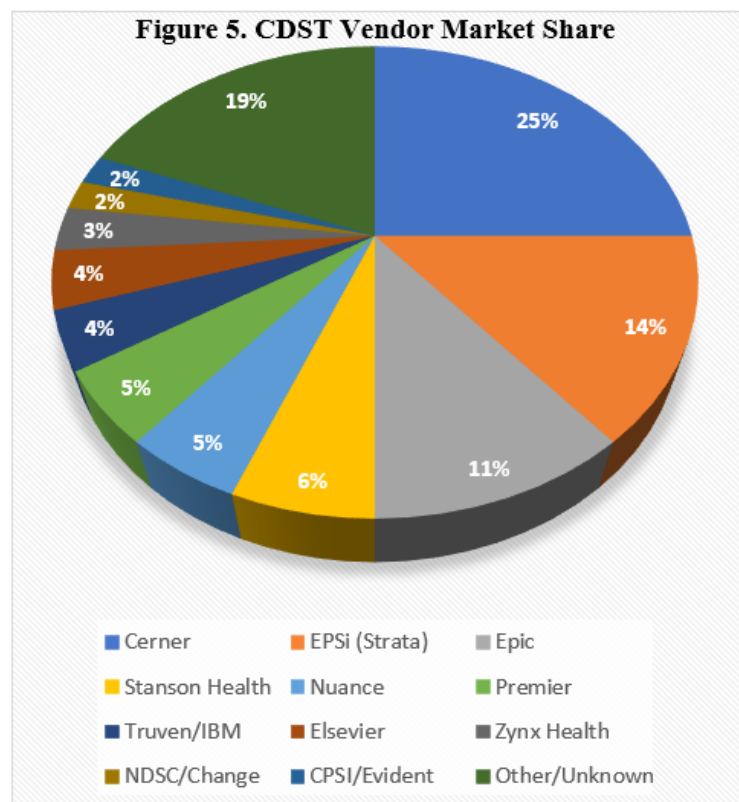[67] Vyas DA, et al., supra note 1; Lytle KS, supra note 16; Feldstein D, et al., supra note 16.
[68] Lee NT, supra note 38.
[69] Mukherjee N, et al., supra note 67.

using science and scientific methods to advance notions of racial inferiority of marginalized racial groups.[70, 71]

Recognizing this mindset was accepted within science and medicine for centuries, researchers have long discouraged assumptions that clinical medicine is inherently objective; rather, many racial differences in outcomes have their foundations in social and structural forces, such as systemic racism and discrimination.[72, 73, 74]

Because Big Data already replicates or amplifies human biases, adding its elements to CDST architecture with questionable foundations can yield unintended, yet avoidable consequences. [75, 76] Furthermore, many CDSTs are proprietary (see Figure 5), making it difficult for independent researchers to evaluate and validate these tools to ensure they function as intended and do not disadvantage certain patients. The potential for clinical algorithms to exacerbate existing disparities does not lay with CDSTs themselves, but in the use of underlying Big Data and the unsubstantiated conscious and unconscious social constructs that inform these tools.

Figure 5. CDST Vendor Market Share

Legend: Cerner, EPSi (Strata), Epic, Stanson Health, Nuance, Premier, Truven/IBM, Elsevier, Zynx Health, NDSC/Change, CPSI/Evident, Other/Unknown

Clinical Decision Support– 2018, REACTION DATA (2019), https://www.reactiondata.com/report/clinical-decision-support-2018/.

For example, one study found an algorithm used to predict broad-based health care risks exacerbated racial inequities, not by using race as a variable, but by relying on health costs as a proxy for health needs.[77] The result of using this proxy variable was that White patients appeared healthier than Black patients with the same risk score for reasons unrelated to

[70] Clayton A, How Eugenics Shaped Statistics, Nautilus (Oct. 28, 2020), http://nautil.us/issue/92/frontiers/how-eugenics-shaped-statistics.
[71] Braun L, et al., supra note 6.
[72] Roberts DE, Abolish Race Correction, 397:10268 Lancet 17—18 (2021).
[73] Ford CL, et al., Critical Race Theory, Race Equity, and Public Health: Toward Antiracism Praxis, 100:1 Am. J. Public Health S30—35 (2010).
[74] Ford CL, et al., Commentary: Just What is Critical Race Theory and What's it Doing in a Progressive Field like Public Health?, 28:1 Ethnicity & Disease 223—230 (2018).
[75] Lee NT, et al., supra note 37.
[76] Lee NT, supra note 38.
[77] Take Racism Out of Medical Algorithms, Scientific American (Dec, 1, 2020), https://www.scientificamerican.com/article/take-racism-out-of-medical-algorithms/.

differences in health status. Further, White patients had higher overall costs due to structural racial inequities that skewed access and treatment in their favor; and despite relatively similar costs of care with other racial/ethnic groups, the study found the needs of Black patients were grossly underestimated.[78, 79] Though the use of race data in health care delivery is pervasive, the insidious effects of racism make it difficult to quickly and easily identify CDSTs that contribute to inequity.

What are some examples of clinical algorithms and the detrimental impact of their use of race?

As shown in the June 2020 study published in the *NEJM*, racial correction in clinical algorithms is harmful for a range of conditions, from childbirth to cancer. Study authors concluded that race had been misinterpreted or misused in multiple CDSTs, resulting in worse outcomes for people of color.[80] These findings echoed general concerns about the tendency of Big Data and data analytics to replicate or amplify human biases that, in many instances, result in some form of disparate outcomes.[81] Foreseeably, the study's findings also resurrected the complicated history between people of color and the medical community, and the sensitive topics of structural racism and discrimination.[82]

According to the *NEJM*, "Many of these race-adjusted algorithms guide decisions in ways that may direct more attention or resources to White patients than to members of racial and ethnic minorities."[83] While the use of race in clinical algorithms is largely driven by differences in health outcomes that are common to large datasets, these differences are most likely due to the effects of racism and other determinants of health, not "biological" effects of one race versus another.[84]

As the researchers cautioned, incorporating race data into clinical algorithms can entrench disparities by potentially producing different treatment approaches for individuals that are not based on precision medicine but are simply chosen because of race/ethnicity, historical differences in outcomes based on race, discrimination, racism, and biases about race.[85] Table 1 provides examples of widely used clinical algorithms and the way their use of race has the potential to exacerbate existing disparities in medical treatment and outcomes, as found in the *NEJM* study.

[78] Id.
[79] Obermeyer Z, et al., supra note 2.
[80] Vyas DA, et al., supra note 1.
[81] Lee NT, et al., supra note 37.
[82] Matthew DB, supra note 18.
[83] Vyas DA, et al., supra note 1.
[84] Id.
[85] Understanding the Basics of Clinical Decision Support Systems, Health IT Analytics (Dec. 12, 2017), https://healthitanalytics.com/features/understanding-the-basics-of-clinical-decision-support-systems; Benjamin R, Assessing Risk, Automating Racism, 366:6464 SCIENCE 421—22 (2019).

TABLE 1. EXAMPLES OF CDSTS AND REPORTED RACIAL INEQUITIES

CDST	Racial and Ethnic Categories	Impact	Clinically Reported Racial Inequity*
Get with the Guidelines: Heart Failure	Black, non-Black	Black patients are systematically scored as lower risk for in-hospital death from heart failure	Black patients have higher rates of heart failure readmission
Vaginal Birth After Cesarean (VBAC)	African American, Hispanic	Black and Hispanic patients predicted to have higher rate of complications when attempting VBAC	Black and Hispanic women have higher rates of birthing morbidity and mortality
Estimated Glomerular Filtration Rate (eGFR) *Note: In September 2021, the National Kidney Foundation and American Society of Nephrology released a report outlining a new approach to diagnosing kidney disease independent of race.*	Black, White, Other	Modifier estimates a healthier level of kidney function for Black patients than that of White patients using the same measured lab result	Black patients are less likely than White patients to be evaluated, identified, and listed as transplant candidates; Black patients are more likely to receive lower quality kidneys and have transplant complications
Pulmonary Function Tests (PFTs)	Captures Race, Ethnicity	Applying a correction factor for Black or Asian patients can result in different timing of diagnosing disease and offering certain treatment options	Black patients have higher rates of asthma, chronic lung disease, and worse outcomes
Osteoporosis Risk SCORE and Fracture Risk Assessment Tool (FRAX)	Osteoporosis Risk SCORE: Black FRAX: Black, Asian, Hispanic	Black patients are scored lower risk for osteoporosis; Black, Asian, and Latino patients are scored as lower risk for fracture	White women have higher fracture rates; Black women have higher rates of morbidity and mortality from fractures

CDST	Racial and Ethnic Categories	Impact	Clinically Reported Racial Inequity*
Short-Term Surgical Risk Calculation (STR)	African American, Asian, American Indian/Alaskan Native, Native Hawaiian/Pacific Islander, or Hispanic, Latino or Spanish; White (default)	Black patients are scored as higher risk for death and complications; Asian, Latino, and Alaskan Native/Pacific Islander patients assumed to have increased risk of complications	Black patients are systematically more likely to get their care at low-quality hospitals
Kidney Donor Risk Index (KDRI)	African American	Kidneys from Black donors rank more likely to fail, less acceptable	Black people are less likely to volunteer to be kidney donors; Black patients are less likely to be identified as transplant candidates
Kidney Stone Risk Prediction (STONE Score)	Black or non-Black	Black patients score as less likely to have a kidney stone than non-Black patients when presenting with abdominal pain	Black patients have worse outcomes from kidney stones
National Cancer Institute Breast Cancer Risk Assessment Tool (NCI BCRA), Breast Cancer Surveillance Consortium Risk Calculator (BCSC) and Rectal Cancer Survival Calculator (RCSC)	NCI BCRA: White, African American, Hispanic/Latina, Asian American, American Indian/Alaska Native, Unknown BCSC: White, Black, Asian, Native American, Other/Multiple Races, Unknown RCSC: White, Black, Other	BCRA and BCSC predict lower five- or 10-year risk of breast cancer for Black, American Indian, Asian, and Latina women RCSC predicts worse survival for Black patients	Women of color have lower rates of screening for breast cancer

*More research is needed to dissect relationships between the algorithm and existing racial inequities

Sources: Vyas DA, et al., Hidden in Plain Sight – Reconsidering the Use of Race Correction in Clinical Algorithms, 383 New Eng. J. of Medicine 874—882 (2020).
Schmidt IM, et al., Separate and Unequal: Race-Based Algorithms and Implications for Nephrology, 32:3 J. Am. Society of Nephrology 529—533 (2021).

The algorithms listed in Table 1 and described in additional detail below are but a few examples of how the misuse of race and ethnicity in CDSTs codify and reproduce racial health inequities. The list is not exhaustive and does not include some proprietary health system CDSTs used in conjunction with EHRs.

Kidney transplant. Black Americans have nearly 3.5 times the rate of End-Stage Renal Disease (ESRD) of White Americans, and Black Americans are less likely than White Americans to be identified as kidney transplant candidates, be referred for evaluation, put on the kidney transplant waitlist, or receive a kidney transplant. Upon transplantation, Black patients are also more likely than White patients to receive lower quality kidneys and have poorer transplant graft survival.[86, 87, 88, 89, 90] In the case of Estimated Glomerular Filtration Rate (eGFR), which calculates kidney function by estimating how much blood passes through glomeruli each minute, the modifier for Black race estimates a level of kidney function for Black patients that appears healthier than that of White patients for the same measured lab result.[91]

A recently released study of patients at Mass General Brigham showed that one-third of Black patients – over 700 people – would have been reclassified to a more severe stage of kidney disease, and 64 Black patients would have met the criteria for referral for transplant evaluation if the race modifier were removed from the eGFR equation.[92] The study quantified the harm to Black patients and connected that harm to an automatic kidney function calculation tool widely used across electronic medical records and laboratories.[93]

In addition, the Kidney Donor Risk Index (KDRI) score, which makes kidneys from Black donors look riskier than those from other donors, could unnecessarily diminish Black kidney donors. Based on current evidence, it is unlikely that Black race is predictive of kidney transplant success but, rather, that unaddressed socioeconomic factors influence outcomes.[94]

Osteoporosis. The Osteoporosis Risk Simple Calculation Osteoporosis Risk Estimation (Osteoporosis Risk SCORE) and the Fracture Risk Assessment Tool (FRAX©) help clinicians stratify the risk of low bone density and bone fracture, respectively. Clinicians use these CDSTs to guide decisions about the most appropriate osteoporosis screening tests and medications that

[86] Patzer RE, et al., The Role of Race and Poverty on Steps to Kidney Transplantation in the Southeastern United States, 12:2 Am. J. Transplant 358—368 (2012).
[87] Epstein AM, et al., Racial Disparities in Access to Renal Transplantation — Clinically Appropriate or Due to Underuse or Overuse?, 343:21 New Engl. J Med 1537—44 (2000).
[88] Kasiske BL, et al., Race and Socioeconomic Factors Influencing Early Placement on the Kidney Transplant Waiting List, 9:11 JASN 2142—2147 (1998).
[89] Mohandas R, et al., Racial and Socioeconomic Disparities in the Allocation of Expanded Criteria Donor Kidneys, 8:12 JASN 2158—64 (2013).
[90] Purnell TS, et al., Reduced Racial Disparity in Kidney Transplant Outcomes in the United States from 1990 to 2012, 27:8 JASN 2511—18 (2016).
[91] Vyas DA, et al., supra note 1.
[92] Ahmed S, et al., Examining the Potential Impact of Race Multiplier Utilization in Estimated Glomerular Filtration Rate Calculation on African-American Care Outcomes, 36:2 J. Gen. Intern. Med. 464—71 (2021).
[93] Simonite T, How an Algorithm Blocked Kidney Transplants to Black Patients, Wired (Oct. 26, 2020), https://www.wired.com/story/how-algorithm-blocked-kidney-transplants-black-patients/.
[94] Tucker KJ, What's Behind Racial Disparities in Kidney Disease?, Harvard Medical School (Feb. 3, 2021), https://www.health.harvard.edu/blog/whats-behind-racial-disparities-in-kidney-disease-2021020321842.

decrease the risk of bone fractures. These tools have led to Black patients being systematically scored as lower risk for osteoporosis, while Black, Asian, and Latino patients are systematically scored as lower risk for fracture. Patients in these marginalized groups may be skipped or otherwise deprioritized for screening and treatment for osteoporosis because clinical teams rely on these CDSTs to inform clinical decision-making. For example, White women have higher fracture rates, but Black women have worse outcomes, including higher rates of morbidity and mortality from fractures.[95]

Cardiac mortality and complications. The Short-Term Risk Calculator (STRC) tool predicts intraoperative mortality and complications for common cardiac surgeries.[96] Clinicians use it to guide decisions on when and how to offer surgery to their patients. In this tool, the default setting is to consider White patients as the baseline while Black patients are systematically scored as higher risk for death and complications.[97] This design element impacts referral rates for surgical evaluation for Black patients and potentially lowers their chance to receive necessary surgical treatment.[98]

For other people of color – Asian, Latino, Alaskan Native/Pacific Islander – the STRC predicts increased risk of complications but not mortality. Black patients have higher rates of mortality after cardiac surgery compared to White patients, but evidence suggests that is largely because Black patients are systematically more likely to get their care at lower quality hospitals.[99] By hardcoding a higher risk score for people of color, racial inequity is embedded in the STRC, then bolstered and reproduced in its risk evaluations of patients. This fact suggests that hospitals using the STRC may incorrectly determine risk for cardiac mortality and complications in patients of color while masking needed improvements in the quality of hospital and surgical care in facilities that predominantly serve these very communities.

Maternal mortality. Black, American Indian, and Latina women have two to three times higher rates of maternal mortality than White women, and the Centers for Disease Control and Prevention determined that two-thirds of pregnancy-related deaths were preventable.[100, 101] In addition to higher mortality rates, Black, American Indian, and Latina women have higher rates of cesarean delivery despite the known health benefits of vaginal delivery. Through the VBAC risk-evaluation tool – which predicts success of vaginal birth after a prior caesarean section – developers note race, ethnicity, insurance status, and other variables as being predictive of outcomes.[102] Black and Latina are the two classifications highlighted for adjustment within the

[95] Cauley JA, Defining Ethnic and Racial Differences in Osteoporosis and Fragility Fractures, 469:7 Clin. Orthop. Relat. Res. 1891—99 (2011).

[96] Online STS Adult Cardia Surgery Risk Calculator: New Version (4.20), Society of Thoracic Surgeons http://riskcalc.sts.org/stswebriskcalc/calculate (last visited July 15, 2021).

[97] Vyas DA, et al., supra note 1.

[98] Id.

[99] Khera R, et al., Racial Disparities in Outcomes After Cardiac Surgery: The Role of Hospital Quality. 17:5 Curr. Cardiol. Rep. 29 (2015).

[100] Cole HE, et al., Building a Movement to Birth a More Just and Loving World, Nat'l. Perinatal Task Force (2018), https://perinataltaskforce.com/heads-up-maternal-justice-npt-2018-report-out-now/.

[101] Data Brief From 14 U.S. Maternal Mortality Review Committees, 2008 – 2017, Ctrs. Disease Control & Prevention (2019), https://www.cdc.gov/reproductivehealth/maternal-mortality/erase-mm/mmr-data-brief.html.

[102] Grobman WA, et al., Development of a Nomogram for Prediction of Vaginal Birth After Cesarean Delivery, 109 Obstet. Gynecol. 806—12 (2007).

VBAC risk calculation tool, but these women are often not informed about how race or ethnicity influence the birthing options clinicians present to them.

Heart failure. The "Get with the Guidelines–Heart Failure" tool predicts risk of in-hospital death for patients with heart failure.[103] Clinicians use it to guide decisions on what treatments to start, such as preserving aggressive treatments for the sickest patients and offering less aggressive treatments for lower-risk patients. The use of this CDST can result in Black patients systematically scoring as lower risk for death, which can lead to both the denial and delay of aggressive heart failure treatments – a fact that results in significant racial inequities such that Black patients often having worse outcomes.[104]

Lung function. Historically, purported differences in measured lung function have been used to justify racism and Black biological inferiority.[105, 106] The machine that measures two aspects of lung function, the spirometer, was created in the 1800s by Samuel Cartwright, a pro-slavery doctor who devoted himself to advancing pseudo-science to justify and defend the abhorrent institution. [107, 108] Today, the spirometer continues to integrate racial prediction factors that adjust lung function metrics for Black and Asian American patients.

Once "corrected" for race, the results and interpretation of the Pulmonary Function Test (PFT) can mean the difference between a patient being diagnosed with a disease, qualifying for certain treatments, being referred to surgery, or going about his/her/their lives untreated. While research into the role of social and environmental factors on measurement and interpretation of PFTs is sparse, studies have produced two important conclusions: 1) the current race-based lung function equation results in significant diagnostic inaccuracies for those who identify as Black, and 2) genetic ancestry, not race, has bearing on lung function.[109] On a national scale, the clinical impact of these racial "correctors" should not be underestimated, especially in an arena where there are known racial inequities in outcomes for asthma and other chronic lung diseases among people of color.[110]

Cancer. The Rectal Cancer Survival Calculator (RCSC), the National Cancer Institute Breast Cancer Risk Assessment Tool (NCIBC), and the Breast Cancer Surveillance Consortium Risk Calculator (BCSC) use race as a part of risk calculation; all three tools score non-White

[103] Peterson PN, et al., A Validated Risk Score for in-Hospital Mortality in Patients with Heart Failure from the American Heart Association Get with the Guidelines Program, 3 Circ. Cardiovasc. Qual. Outcomes 25—32 (2010).

[104] Eberly LA, et al., Identification of Racial Inequities in Access to Specialized Inpatient Heart Failure Care at an Academic Medical Center. 12:11 Circ Heart Fail.ve006214v (2019).

[105] Washington HA, Medical Apartheid: The Dark History of Medical Experimentation on Black Americans from Colonial Times to the Present (Harlem Moon: New York 2008).

[106] Braun L, Breathing Race into the Machine: The Surprising Career of the Spirometer from Plantation to Genetics (Univ. of Minnesota Press 2014).

[107] Id.

[108] On this Day – March 17, 1851Pro-Slavery Doctor Claims Enslaved People's Desire to Be Free Is "Curable Mental Disease", Equal Justice Initiative https://calendar.eji.org/racial-injustice/mar/17 (last visited July 15, 2021).

[109] Kumar R, et al., Genetic Ancestry in Lung-Function Predictions. 363:4 New Engl. J. Med. 321—30 (2010).

[110] Assari S, et al., Race, Ethnicity, Socioeconomic Status, and Chronic Lung Disease in the U.S., 5:1 Res. Health Sci. 48—63 (2020).

patients differently than White patients.[111, 112, 113] The RCSC predicts worse survival for Black patients, which may lead clinicians to offer less aggressive treatment options to these patients. The NCIBC and BCSC both predict lower five- and 10-year risk of breast cancer for Black, American Indian, Asian American, and Latina women, which reduces frequency of breast cancer surveillance and may delay early diagnosis of breast cancer. Rectal cancer and breast cancer (as well as other cancer) outcomes are worse for people of color.[114, 115] Risk prediction tools like these mute or omit the role of social determinants of health in outcomes when offering clinicians guidance on screening and treatment options.

What can be done?

The implications of the misuse of race in clinical algorithms are profound for medical education, clinical education, research, and, ultimately, patient outcomes. Researchers have demonstrated that false beliefs in a biological basis for race negatively impact clinical care through racial biases that influence everything from pain assessment to treatment.[116] The genesis of adjusting kidney function based on the patient's race, for example, is in research that neither questioned whether race was based in science or societal norms nor critically examined how race correction in medicine would normalize unfounded racial biases.[117]

Spurred by the growing body of research examining how CDSTs may amplify inequities and an international conversation about racial justice, change appears to be on the horizon. Professional medical societies can play a key role in transforming the way clinicians think about and use CDSTs by leading this overdue reexamination of racial equity and positioning of race/ethnicity data in CDSTs. Several prominent institutions, such as Beth Israel Deaconess Hospital, Mass General Brigham, University of California San Francisco, University of Washington, and Vanderbilt University Medical Center, ended the practice of race correction in kidney function in 2020.[118] These institutions offer roadmaps for others to use as awareness builds about the potential for ill effects associated with CDSTs left unchecked.

[111] Bowles TL, et al., An Individualized Conditional Survival Calculator for Patients with Rectal Cancer, 56 Dis. Colon Rectum 551—59 (2013).

[112] National Cancer Institute, Breast Cancer Risk Assessment Tool, Nat'l Inst. Health, https://bcrisktool.cancer.gov/calculator.html (last visited July 16, 2021).

[113] Tice JA, et al., Breast Density and Benign Breast Disease: Risk Assessment to Identify Women at High Risk of Breast Cancer, 33 J. Clin. Oncol. 3137 —43 (2015).

[114] Mariotto AB, et al., Geographical, Racial and Socio-Economic Variation in Life Expectancy in The Us and Their Impact on Cancer Relative Survival, 13 PLoS One e0201034 (2018).

[115] Freedman RA, et al., Trends in Racial and Age Disparities in Definitive Local Therapy of Early-Stage Breast Cancer, 27 J. Clin. Oncol. 713—19 (2009).

[116] Hoffman KM, et al., supra note 7.

[117] Braun L, et al., supra note 6.

[118] Godoy M, Is It Time for a Race Reckoning in Kidney Medicine?, NPR (Dec. 28, 2020), https://www.npr.org/sections/health-shots/2020/12/28/949408943/is-it-time-for-a-race-reckoning-in-kidney-medicine.

FINDINGS

In the fall of 2020, Chairman Neal sent letters to professional societies describing the inequities embedded in CDSTs and requested feedback on addressing these inequities. The professional societies were selected based on each organization's relationship to the CDSTs identified in the NEJM study. According to the American Association of Medical Colleges (AAMC), the U.S. has a total of about 893,000 practicing physicians.[119] Combined, membership of the professional societies the letters targeted represents approximately 503,300 physicians and researchers, including some allied health professionals.

Chairman Neal followed these letters with a broader RFI seeking insight on three questions:

1. To what extent is it necessary that health and health-related organizations address the misuse of race and ethnicity in clinical algorithms and research? What role should patients and communities play?

2. What have been the most effective strategies that you or your organization have used to correct the misuse of race and ethnicity in clinical algorithms and research, if any? What have been the challenges and barriers to advancing those strategies?

3. What strategies would you propose to build consensus around guidelines that could be adopted broadly across the clinical and research community to end the misuse of race and ethnicity in clinical algorithms and research?

The Chairman's letters and RFI generated 31 responses, with suggestions and recommendations from stakeholders across the U.S. (see Appendix B, Table 3 for a list of respondents). Due to the two data collection tools – targeted letters and a broader RFI – Ways and Means staff conducted two separate analyses, discussed separately, below. (See Appendix A for a detailed description of the methodology and limitations employed to generate the analysis of these responses.)

The Committee's October 2020 RFI solicitation (see Appendix B, Table 4, for a full list of RFI respondents) generated 18 responses from stakeholders representing academic institutions (3), additional professional societies (7), health systems (1), among others. Respondents represented a spectrum of experiences in clinical medicine from trainees to tenured faculty and included a diverse range of specialties and professions, including psychiatry, physical therapy, cardiology, family medicine, pediatric nephrology, surgery, transplantation, and internal medicine. Physician-led organizations made up the largest cohort of respondents (8). Nine of the 18 responding organizations stated that health equity; racial disparities; or the interests of Black, Indigenous, and other communities of color were explicitly part of their mission, research, and/or scope of work.

[119] Physician Specialty Data Report 2017, Am. Assoc. Medical Colleges, https://www.aamc.org/data-reports/workforce/interactive-data/number-people-active-physician-specialty-2017 (last visited July 16, 2021).

Organization & Professional Society Responses

The Committee on Ways and Means staff analysis of the responses from the 13 organization and professional society responses yielded several key themes and recommendations that we describe in detail below.

Raise awareness about health inequities to ensure diversity of leading voices on health equity. All respondents noted the importance of raising awareness about health inequities among their membership. Specifically, they reported a broad spectrum of approaches and platforms that could be used to address this goal by implementing trainings, task forces, briefings, declarations, research grants, and clinical practice guidelines. The Accreditation Council for Graduate Medical Education (ACGME), stated that: "Because [we do] not set specific curricula, the ACGME is working with Sponsoring Institutions and programs to provide examples of systems-based practice that demonstrate understanding of racialized clinical algorithms."

> *"The ATS [American Thoracic Society] acknowledges that by recommending race-specific reference equations for pulmonary function estimates, it has had a role in the continuation of the use of race in a manner that ignores the effects of structural racism."*
>
> — ATS

Some professional societies also reported longstanding efforts to increase diversity within their professions; however, many initiatives reported were emergent and there was less clarity about how health equity experts were leading strategy and priorities within their organizations. Approaches respondents described employing to address diversity included creating new positions to focus on diversity and developing task forces, awards, scholarships, working groups, and mentorship and pipeline programs. Responses did not discuss strategies to prioritize integrating health equity into organizational strategic plans. The American Medical Association (AMA) specifically noted that in 2008 it "issued an apology to the NMA [National Medical Association] for allowing the exclusion of Black physicians for over 100 years."

> *"ACOG [American College of Obstetricians and Gynecologists] has not and does not endorse the VBAC risk calculator, nor its use of race in its algorithm."*
>
> — ACOG

Reevaluate the use of race variables and ethnicity in the design, execution, and evaluation of clinical algorithms. Several societies voiced interest in working in a coalition with other societies to develop a collaborative approach and/or task force to reevaluate the use of race and ethnicity in clinical algorithms. The American College of Obstetricians and Gynecologists (ACOG) noted that it had already formed a coalition working on health care delivery, focused on integrating equity into all quality improvement policies.

Some societies felt that the unintended consequences of changing the use of race and ethnicity in tools must be researched and considered further before undertaking wholesale changes. "Data and expertise from NIH [National Institutes of Health] or other relevant stakeholders about how e-GFR is used across the various sectors of healthcare would be key to understanding the implications of changes to the calculation on transplant and non-transplant patients alike," United Network for Organ Sharing (UNOS) said.

In contrast, several societies said they were not planning to reevaluate the way their relevant CDSTs use race because their organization did not play a role in creating the algorithm and, thus, it was not their responsibility to reevaluate it. Still, they said, they believed the algorithms are grounded in a solid evidence base. "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," the Society of Thoracic Surgeons (STS) said. Others stated that they have already made significant progress on racial inequities and that a reevaluation of the use of race in clinical algorithms was not necessary. Finally, some societies noted that CDSTs can decrease racial inequities in some instances and that race is often used as a proxy for social determinants of health.

Refine approaches to communicating with and engaging clinicians. Most societies explicitly referenced or endorsed the statement, "race is a social construct," some noting organizational reports or policies already disseminated on the issue. ACOG said it is conducting a comprehensive review to stop the use of race as a biological factor. Others said they are planning to publish guidance in the near future based on the recommendations of dedicated groups reviewing the issue.

> *"ASN [American Society of Nephrology] agrees that unlike age, sex, and body weight, race is a social, not a biological, construct. Adjusting for race in the eGFR equation may not address the diversity within self-identified Black or African-American patients as well as other racial or ethnic groups."*
>
> — ASN

Several societies recommended further consideration of the unintended consequences of removing race from CDSTs. Others suggested conferences, summits, committees, practice bulletins, training for fellows, and further research as ways to help raise awareness about the misuse of race in these tools. Finally, three societies suggested reconsidering the use of race and ethnicity in EHRs while concurrently reviewing the extensive number of risk models that are constantly created and updated.

> *"As progress is made in the identification of biologic markers, it is our hope that the use of racial factors per se in clinical tools will become anachronistic … ASTS [American Society of Transplant Surgeons] agrees that it is very important to eliminate race correction in the eGFR calculation."*
>
> — ASTS

Encourage transparency in communicating with patients about CDSTs and their inherent limitations. Few societies addressed this question of communicating with patients. Some suggested disseminating information directly to patients and communities, while others suggested training providers to inform patients. The American Society of Nephrology (ASN) emphasized the role of patient-led organizations: "By partnering with [the National Kidney Foundation] NKF, as a patient organization, ASN will help ensure that these recommendations, and the multiple social and clinical implications, are conveyed in the most patient-centered manner possible, such as potentially NKF's patient-facing communications platforms."

Identify prospective remedies to ensure access for patients. Few societies responded to this question directly. Several suggested removing race and ethnicity data from the clinical algorithms, while others suggested rethinking their inclusion. Others proposed acknowledging race-related risks for patients, focusing on population health, communicating the changes in clinical algorithms to patients once implemented, and implementing algorithms that are shown to decrease inequity.

> *"...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."*
>
> — STS

Advance the role that the federal government could play in ensuring equitable and inclusive clinical algorithms. A few professional societies suggested cultural competency training, research on its effectiveness, and funds for increasing diversity in medicine as worthwhile endeavors at the federal level. Others suggested analyzing algorithms the federal government uses for evidence of bias and providing more funding for disparities research writ large. Societies highlighted the need for the Department of Health and Human Services (HHS) and the VA to implement health equity quality metrics. Societies suggested increasing payment coverage for earlier screening and chronic disease coverage, as well as the expansion of broadband and telehealth. Many of these suggestions align with strategic areas of focus the Committee highlighted in the majority staff report *Left Out: Barriers to Achieving Health Equity in Rural and Underserved Communities*.

> *"At its core, rectifying the clinical algorithms and guidelines is a process best left to the specialty societies via a process of careful data analysis and periodic reevaluation."*
>
> — AMA

Determine the role organizations and professional societies could play. Several societies described the need to revise publication standards to ensure they do not reinforce racism and the need to reevaluate research priorities to focus on new health equity research areas. Others suggested using social determinants of health data as a replacement for use of race and reevaluating algorithms and predictive models. ACOG specifically mentioned efforts to review all clinical guidelines and standards to examine how the organization uses race and ethnicity. Earlier this year, ACOG led the women's health medical community in committing to a comprehensive review of scholarship, clinical documents, research, and publications guidelines that it produces or directs to ensure that when race is referenced in clinical documents or scholarship that it is not treated as a biological risk factor," ACOG wrote. Other suggestions included focusing on individualized care and quality improvement and using task forces and policy statements to change practice.

Request for Information Responses

Committee staff also performed a qualitative analysis on the responses to each question outlined in the RFI. Summaries of the emergent themes and notable quotes are described below.

Organizations must address clinical algorithms and research. Respondents noted that misdiagnoses are quite common because race and ethnicity are often misused; that this misuse could be related to the lack of disaggregated data; and that it must be countered with training on the history or racism in medicine, structural racism, anti-racist policy, race-conscious health care, and organizational self-assessment. The Association of Black Cardiologists wrote that it "is aligned with the assessment that race has been misinterpreted and misused in clinical care algorithms with consequent harm to communities of color. Organizations highlighted the need to follow the recommendations of longstanding health equity scholars who interrogate racism, not race. For example, the Center for Surgery and Public Health noted, "While genetic ancestry can provide useful information in certain disease processes, such as sickle cell and Tay Sachs, it poorly correlates with race/ethnicity categories." Mass General Brigham noted that the use of race reinforces racist approaches to classification, while the Society of General Internal Medicine noted the need for more research on the benefits and harms of ending the practice.

> *"The use of race-based algorithms is clinically inaccurate, medically dangerous, and negatively affects clinical care."*
>
> — Brown University

> *"Even if patient race is self-reported, we are certainly not informing patients that such information will be used to adjust their clinical care – which many (if not most) patients would find entirely unacceptable"*
>
> — Mass General Brigham

Diverse patients and communities must be involved in the clinical trials and research of emerging tools. A majority of respondents mentioned the importance of racially diverse stakeholders for clinical trials, surveys, other research, and partnerships. Respondents from Brown noted the significant negative psycho-emotional effects racism has on patients: "The same patients who are being input into these algorithms without context or thought for negative outcomes are the people who are carrying the physical, mental and emotional burden of individual and structural racism." Others highlighted the proprietary nature of algorithms and suggested that patients should have access to their data and be involved in decision support tool validation and feedback.

Strategies must be enacted to proactively correct the misuse of race and ethnicity in clinical algorithms and research. Several respondents suggested transforming medical training, including the history of racism in curricula, and increasing racial diversity among health professionals. Others advocated for eliminating the use of race correctors and ensuring that race is not a proxy for biology but, rather, a risk. Of note, the American Academy of Family Physicians suggested a need for the "establishment of standards and guidelines on the appropriate use of race in scientific research and conditioning the receipt of federal research funding on compliance."

> *"Our journal publications will no longer accept manuscripts from authors whose findings indicate biological differences by race without further justification."*
>
> — American Academy of Family Physicians

> *"Clinicians and scientists must distinguish between the use of race in descriptive statistics, where it plays a vital role in epidemiologic analyses, and in prescriptive clinical guidelines, where it can exacerbate inequities."*
>
> — American Psychiatric Association

Practitioners, researchers, and the government must confront challenges and barriers to implementing strategies to reduce the misuse of race/ethnicity in clinical algorithms. Respondents noted several challenges, including the fact that race correction and misuse of race in exam questions leads to racially biased labeling, stereotypes, and judgements by clinicians – patterns that have been shown to last for up to 20 years after training. Others noted that anti-racist research methods and collaboration with medical professional societies is needed to change provider behavior. The lack of self-reported racial data, more holistic data, and data from patients with limited information technology knowledge and access are major challenges as well. Lastly, respondents noted the pervasiveness of misuse of race/ethnicity, such as the fact that 90 percent of laboratories use race correction in kidney function.

More consensus from adopters of clinical algorithms must be promoted to make substantive changes. Respondents pointed to bodies and agencies like the National Academy of Medicine, the Centers for Medicare & Medicaid Services (CMS), and other federal offices as necessary leaders in publishing guidelines on appropriate use of race/ethnicity and that medical societies should help build consensus. Additional research funding to eliminate inequities and a federal government declaration of racism as a public health crisis could buoy such efforts. Lastly, refining CDSTs with more data, including the social determinants of health, would help correct for bias and should encourage developers to co-create algorithms with clinicians, respondents said.

> *"A growing body of evidence shows training programs imprint practice behaviors that can be detected nearly 20 years later, therefore, the misuse of race and ethnicity in these training institutions not only impacts the clinical service and research at these organizations today, it will impact health care and disparities for decades to come."*
>
> — Beyond Flexner Alliance

Association, Professional Society, and RFI Responses: Areas of Agreement and Divergence

Committee staff also performed a cross-cutting analysis that aggregated responses from organizations and professional societies that received a letter from the Chairman and organizations that responded to the RFI. Areas of concordance and discordance are presented below.

Current practices related to the use of race and ethnicity in CDSTs. While most respondents noted that race is a social construct and agreed that the use and misuse of race and ethnicity in clinical algorithms needs to be reevaluated, the analysis revealed more divergent opinions on the current practices related to use of race and ethnicity data in clinical decision tools than similarities. Professional societies were more likely to respond that they are already addressing the issue of race and ethnicity data misuse in clinical decision-making, while RFI respondents suggested that more leadership from professional societies is needed to build

consensus. Professional societies often suggested more research is needed before decisions can be made, and the unintended consequences of removing race correctors needs further evaluation. In fact, about one-third of organization and professional society respondents said they are not planning to reevaluate the use of race and ethnicity in clinical algorithms. By contrast, RFI respondents tended to advocate for immediate removal of race correctors.

Implementing change in the medical community. None of the professional societies made commitments to improving specific racial health inequities. Professional societies focused heavily on organizational efforts to increase racial and ethnic diversity in their field and support for researchers from communities of color, but the connection between those efforts and the disparities caused by misusing race and ethnicity in CDSTs was not always clear. Several professional societies made commitments to form committees, roundtables, and task forces to take a closer look at this issue. Others noted their interest in collaborating across organizations to increase consensus and develop shared solutions.

Levers for public awareness and a federal role. Professional societies and RFI respondents alike described platforms for medical education and continuing education as important levers for raising awareness about these issues and making change. Research has shown that medical school curricula use terminology for race that is confusing and inconsistent; that differences in burden of disease between racialized groups is presented without context; that minority race is linked with pathology; and that race-based clinical guidelines taught without information about their origins and evidence-base reinforce the misconception of racial biological differences.[120] Across the board, respondents said they believed that federal leadership, levers for accountability for health equity, and funding for research and training are needed to address the issue. Specifically, there was consensus among respondents that enforceable research standards on appropriate use of race and ethnicity and measurement of the effects of racism are critical.

[120] Amutah C, et al., Misrepresenting Race - The Role of Medical Schools in Propagating Physician Bias, 384 New Engl. J. Med. 872—78 (2021).

DISCUSSION

At this time of renewed focus on health equity and racial justice against the backdrop of the COVID-19 pandemic, health care organizations are reevaluating the way long-entrenched practices and processes have exacerbated – and will continue to exacerbate – existing inequities if nothing changes. As the findings from this report show, there is a need and desire for professional medical societies to lead the way in a critical reexamination of how race and ethnicity data, when used improperly in CDSTs, can create worse outcomes for patients of color. Still, as the analysis of the responses to the RFI demonstrated, divergent opinions on the appropriate use of race and ethnicity in CDSTs make it difficult to develop broad consensus that would uniformly transform behavior across the medical community.

Ultimately, we know that it is not race itself that leads to higher rates of complications for Black and Latina women who opt for vaginal birth after cesarean section. We also know that race is not the reason for higher rates of complication from cardiac surgery for people of color, or risk of having a kidney stone when presenting with abdominal pain. Nor is it skin color that explains why some research has found different levels of kidney function for different racial groups, or why lung function varies between groups. Other factors, most of which are avoidable social and structural determinants of health, are the actual root causes of observed differences among racial groups. Yet, this complex socioeconomic web is too often reduced to the fabricated, crude, and convenient construct of race.

We cannot immediately change some of the systemic conditions that block the equitable delivery of health care, but through purposeful pursuit of racial and economic justice, we can transform how we approach the social contract with those who call the U.S. home. Policies to advance equity as described in the Committee on Ways and Means majority staff report *Something Must Change: Inequities in U.S. Policy and Society* and the legislative priority framework *A Bold Vision for a Legislative Path Toward Health and Economic Equity* offer some initial guiding steps.

As the responses analyzed in this report highlighted, the scientific and medical communities have much work to do to achieve consensus on a path forward. More research on the benefits and risks of changing how race and ethnicity are used in CDSTs will be helpful, but evidence of the harms of this practice are growing. Some researchers have observed that there are alternative CDSTs that do not use race and perform well when compared to the current equations that do (mis)use race.[121] In addition, studies also show that immediately removing race correction in kidney function would avert delays in transplant care for Black patients by several years.[122]

Health care delivery and technology continue to expand the scope of their interactions, especially as we move toward value-based payment and seek to make administrative aspects of

[121] Diao JA, et al., In Search of a Better Equation - Performance and Equity in Estimates of Kidney Function, 384 New Engl. J. Med. 396—99 (2021).
[122] Boulware LE, et al., Systemic Kidney Transplant Inequities for Black Individuals: Examining the Contribution of Racialized Kidney Function Estimating Equations, 4:1 JAMA Netw. Open e2034630 (2021).

care delivery more efficient.[123, 124] Much of the theory for success of value-based health care relies on the unique distinction of arrangements and data that offer clinicians a full view of patients, their lifestyles, employment, fitness, and other factors.[125] For those who tout the administrative benefits of CDSTs used to aid in diagnosis and treatment options, the speed and efficiency of these tools are critical to maximizing the availability of resources to deliver care. Thus, harnessing the potential of *properly* applied Big Data and analytics as part of the continued progression to value-based health care and streamlined operations is a critical part of success in both areas.

While this report is focused on CDSTs, the concerns related to inherent bias within medicine extend further. For example, the medical community does not have an ideal alternative to updating modern pulse oximeters, a device that is three times more likely to miss low blood oxygen levels in Black patients compared to White patients. This discrimination in output fuels disparities in health outcomes – all because the device uses infrared light absorption readings that differ with varying degrees of melanin. This fact should motivate clinical professionals and product developers to find better methods of measurement, but instead pulse oximeters – invented in the early 1970's and widely used by the 1980's – have become one of the latest *recognized* health inequities that has negatively affected melanated bodies for nearly half a century.[126, 127]

The negative impact that the stereotyping some medical professionals and trainees still apply to patients of color should not be underestimated. Provider confusion about the biological and social implications of race and ethnicity is a source of harm that the medical community must publicly acknowledge. The field must also prioritize commitments to specific improvements in racial inequities, mechanisms for accountability, and meaningful changes in systems of medical education and continuing education. Levers to make many of these changes already exist within professional societies and health systems as demonstrated in the responses to the Chairman's letters and RFI solicitation.

Ultimately, data on race and ethnicity should be used to measure the social and health impact of racism – not for biological racial distinctions. Overall, health care must be race-conscious – rather than race neutral or colorblind – if it is to succeed in ending racial health inequities. Professional societies and stakeholders in the medical community should follow the lead of health equity scholars to achieve consensus across the community. In tandem, where the federal government can, it must proactively work to avoid endorsing research that embeds racial and ethnic bias.[128] The Committee on Ways and Means remains prepared to support those efforts and to develop mechanisms for accountability of medical organizations for improving racial health inequities and ultimately ending them.

[123] UCSF, Fortanix, Intel, and Microsoft Azure Utilize Privacy-Preserving Analytics to Accelerate AI in Healthcare, Bussinesswire (Oct. 17, 2020), https://www.businesswire.com/news/home/20201007005922/en/UCSF-Fortanix-Intel-and-Microsoft-Azure-Utilize-Privacy-Preserving-Analytics-to-Accelerate-AI-in-Healthcare.

[124] Jain A, et al., The Emergence of Value-Based Health, IBM (2019), https://www.ibm.com/downloads/cas/N2NNWYXG.

[125] Id.

[126] Sjoding MW, et al., Racial Bias in Pulse Oximetry Measurement, 383:25 New Engl. J. Med. 2477—78 (2020).

[127] Severinghaus JW, et al., Discovery of Pulse Oximetry, 105:6 Anesthesia & Analgesia 1—4 (2007).

[128] Neal RE, et al., Racial Health Inequities and Clinical Algorithms, 16:7 CJASN 1120—21 (2021).

CONCLUSION

During the last 60 years, advances in science and medicine have brought life-saving diagnostics and treatment to Americans and the world, but the context in which these advances occurred is critical to understand. In 2021, the widely broadcast and pervasive murders of unarmed Black Americans, along with the disproportionate impact of COVID-19 on communities of color, are but two examples of the how indomitable and varied the effects of racism are on this country. Science and medicine are not immune from these effects, but the commitment to objective, reproducible results and doing no harm suggest the possibility for meaningful shifts toward more just outcomes.

Health equity experts believe that removing race correctors and integrating variables that consider social and structural forces would make CDSTs more accurate while also improving racial health inequities. Within the medical community, there are questions as to whether any of these actions would result in meaningful progress toward health equity and racial justice. The actions of professional societies and associations will be critical to addressing the embedded issues, and there is growing response to the need for their leadership on these and related issues.[129] As the clinical medicine community seeks to find areas of consensus and address areas of divergence on the (mis)use of race in clinical algorithms, the optimal health and wellbeing of patients of color hang in the balance.

In February 2021, the Biden Administration issued an RFI on the "Use of Clinical Algorithms that Have the Potential to Introduce Racial/Ethnic Bias into Healthcare Delivery" through the Agency for Healthcare Research and Quality (AHRQ).[130] According to the RFI, the agency is seeking input "on clinical algorithms that are used or recommended in medical practice and any evidence on clinical algorithms that may introduce bias into clinical decision-making and/or influence access to care, quality of care, or health outcomes for racial and ethnic minorities and those who are socioeconomically disadvantaged."

Further, CMS has solicited public comments on health equity, including racial equity, in each of the payment rules issued since President Biden issued the Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government on January 20, 2021.[131] This solicitation is an important step for HHS, the federal government's leading voice for health care payment and delivery. These efforts are in concert with many of the

[129] AMA Releases Plan Dedicated to Embedding Racial Justice and Advancing Health Equity, Am. Med. Assoc. (May 11, 2021), https://www.ama-assn.org/press-center/press-releases/ama-releases-plan-dedicated-embedding-racial-justice-and-advancing.

[130] Effective Health Care Program: Algorithms Bias Healthcare Delivery, Agency Healthcare Research & Quality, https://effectivehealthcare.ahrq.gov/webform/products/algorithms-bias-healthcare-delivery/submit-info (last visited July 16, 2021).

[131] Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government, White House (Jan. 20, 2021), https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/.

concerns Chairman Neal voiced in a request to the Center for Clinical Standards and Quality (CCSQ) within CMS to explore this issue within its programs.[132]

Moving forward, the Committee on Ways and Means will continue to prioritize health and economic justice and racial equity, including advancing anti-racism, anti-bias, and anti-discrimination positions and policies.[133, 134] The Committee stands ready to bring attention to this issue and work with stakeholders to find solutions that ensure the promise of racial equity is fulfilled.

[132] Chairman Neal Calls on The Trump Administration to Explain Use of Clinical Algorithms in CMS Programs, Committee on Ways & Means (Oct. 14, 2020), https://waysandmeans.house.gov/media-center/press-releases/chairman-neal-calls-trump-administration-explain-use-clinical-algorithms.
[133] Majority Staff Report: Something Must Change: Inequities in U.S. Policy & Society, Committee on Ways & Means (Jan. 2021), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/WMD%20Health%20and%20Economic%20Equity%20Vision_REPORT.pdf.
[134] Policy Pillars & Priorities: A Bold Vision for a Legislative Pathway Toward Health & Economic Equity, Committee on Ways & Means (Jan. 2021), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/FINAL%20WMD%20Health%20and%20Economic%20Equity%20Vision%20Policy_FRAMEWORK.pdf.

APPENDIX A: METHODS AND LIMITATIONS

Below, we describe the methodology used to construct our analytic file and conduct the analyses for this review; we also present limitations.

On September 3, 2020, House Ways and Means Committee Chairman Richard E. Neal called on the leaders of several key professional societies to partner with the Ways and Means Committee in addressing longstanding racial inequities in our society as they relate to clinical algorithms.[135] The letters described how racism has influenced the use of race and ethnicity in medicine, science, and research – and they called for a new path forward where medicine considers race as a tool to measure racism, not biological differences. Chairman Neal detailed the relevant work of each organization and professional society and asked for their perspectives on a series of questions related to their unique medical expertise.

Not long after Chairman Neal sent the organization and professional society letters, other stakeholders in the health equity and racial justice community expressed a desire to provide input to the Committee on the misuse of race and ethnicity in clinical algorithms. Such inquiries spurred Chairman Neal to solicit input and recommendations more broadly through a formal Request for Information (RFI) process on September 17, 2020.[136]

Organization & professional society letters and RFI solicitation development. Ways and Means staff created a broad series of questions to guide organizations, professional societies, and RFI respondents, focusing on the range of issues raised both in the June 2020 report, Left Out: Barriers to Achieving Health Equity for Rural and Underserved Communities, and the extant medical and sociological literature (see Table 2 below.[137] The letters and RFI solicited information from stakeholders representing a broad range of perspectives (e.g., academia, health equity policy organizations, individuals, health equity experts, etc.) across the continuum of care; RFI respondents are listed in Table 4 in Appendix B. Staff ensured that the questions were aligned with those health equity experts were asking to ensure questions were framed in an objective and relevant fashion, the inquiry did not have significant subject-matter gaps, and the questions were flexible enough not to limit relevant ideas.

[135] In a Series of Letters, Neal Calls on Professional Medical Societies to Push Racial Health Equity Agenda Forward, supra note 12.

[136] Ways and Means Committee Issues Request for Information on the Misuse of Race Within Clinical Care, supra note 13.

[137] Left Out: Barriers to Achieving Health Equity for Rural and Underserved Communities, Committee on Ways & Means (July 2020), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/WMD%20Health%20Equity%20Report_07.2020_FINAL.pdf.

TABLE 2. STAKEHOLDER INPUT SOLICITED THROUGH THE RFI [138]

1. To what extent is it necessary that health and health related organizations address the misuse of race and ethnicity in clinical algorithms and research? What role should patients and communities play?

2. What have been the most effective strategies that you or your organization have used to correct the misuse of race and ethnicity in clinical algorithms and research, if any? What have been the challenges and barriers to advancing those strategies?

3. What strategies would you propose to build consensus around guidelines that could be adopted broadly across the clinical and research community to end the misuse of race and ethnicity in clinical algorithms and research?

Analysis. Staff downloaded all relevant responses into a database and created an Excel-based analysis matrix for summarizing and analyzing results. This database sought to capture both quantitative elements of respondents (e.g., type of organization) and qualitative responses (i.e., narrative responses to the questions). The analytic tool mapped to the questions in the organization and professional society letters and the RFI to facilitate cross-respondent analyses. One staff member culled and summarized each response, inputting the summaries into the Excel database to create an analytic file. Once the file was fully populated, two Ways and Means staff members independently reviewed the results to identify emergent themes. These two independent reviews were aggregated and reconciled to develop the results presented in this report.

Limitations. This analysis included several key limitations. First, the sample of respondents is inherently limited to the organizations that heard about and had the resources to respond to the RFI in a timely manner and the professional societies that received personalized letters requesting response. There are likely a number of organizations with experience relevant to the RFI that did not ultimately submit responses to the inquiry. And further, the voluntary nature of the responses to the RFI inherently yielded a selection bias in participants – namely, those most invested and interested in issues pertaining to health equity and clinical algorithms. Second, the Committee limited the length of the RFI responses to three pages. The purpose of this directed approach was to facilitate cross-stakeholder analysis; yet, it had the potential to limit the type and depth of information presented to the Committee. Fourth, after the Committee announced the organization and professional society letters and RFI, researchers published new research that, while providing additional insight for the analysis, were neither incorporated into the initial questions the Committee posed to stakeholders nor in the responses themselves. Finally, given the breadth of information provided to the Committee, the analysis required individual staff members to make a series of judgement calls when summarizing materials. While staff sought to employ an objective and standardized approach to its review of all submissions, there were likely some inevitable inconsistencies in approach.

[138] Letter to Health Stakeholders, Committee on Ways & Means (Sept. 17, 2021), https://waysandmeans.house.gov/sites/democrats.waysandmeans.house.gov/files/documents/ClinicalCorrectorsinvitation_final.pdf.

APPENDIX B: SUPPLEMENTAL TABLES

TABLE 3. ORGANIZATIONS AND PROFESSIONAL SOCIETIES WHO RECEIVED AN INQUIRY AND THEIR RELATED CLINICAL ALGORITHMS

Organization or Professional Society (Acronym)	Membership	Relevant Clinical Algorithm
American College of Cardiology (ACC)	54,000 members who identify as cardiovascular care professionals	Get with the Guidelines: Heart Failure
American College of Emergency Physicians (ACEP)	40,000 emergency physician members	Kidney stone risk prediction
American College of Obstetricians and Gynecologists (ACOG)	60,000 Obstetrician-Gynecologists and other health care professionals dedicated to the provision of women's health	Vaginal Birth After Cesarean
Accreditation Council for Graduate Medical Education (ACGME)	865 ACGME-accredited institutions sponsoring approximately 12,000 residency and fellowship programs in 182 specialties and subspecialties	Medical education standards for teaching clinicians how race and ethnicity should and should not be used
American Heart Association (AHA)	40 million volunteers and 2,800 employees; nearly 100-year-old organization devoted to public health	Get with the Guidelines: Heart Failure
American Medical Association (AMA)	240,000 members, oldest physician professional society	Multiple algorithms across specialties
American Society of Clinical Oncology (ASCO)	45,000 clinical oncologists, researchers, and other oncology professionals who treat patients with cancer across the country	Breast cancer and rectal cancer risk

Organization or Professional Society (Acronym)	Membership	Relevant Clinical Algorithm
American Society of Nephrology (ASN)	21,000 nephrologists, scientists, and other kidney health care professionals	Estimated glomerular filtration rate
American Society of Transplant Surgeons (ASTS)	1,800 professionals dedicated to excellence in transplantation surgery	Kidney donor risk index
American Thoracic Society (ATS)	16,000 members originally founded in 1905 as a consortium to prevent, control, and treat tuberculosis	Pulmonary function tests
The Endocrine Society (ES)	18,000 experts in all research and clinical aspects of hormone health, including osteoporosis and bone health	Bone density screening
Society of Thoracic Surgeons (STS)	7,500 surgeons, researchers, and allied health care professionals worldwide	Short-term surgical risk calculation
United Network for Organ Sharing (UNOS)	Network of regionally focused organizations that facilitate transplant by organizing organ procurement	Kidney donor risk index

TABLE 4. RFI RESPONDENTS AND ORGANIZATIONAL DESCRIPTION

Organization	Organization Description
American Academy of Family Physicians (AAFP)	Represent 136,700 family physicians and medical students
American Physical Therapy Association (APTA)	100,000-member physical therapists, physical therapist assistants, and students of physical therapy.
American Psychiatric Association (APA)	National medical specialty association representing over 38,500 psychiatric physicians.
American Society of Pediatric Nephrology (ASPN)	Professional society founded in 1969 and composed of pediatric nephrologists whose goal is to promote optimal care for children with kidney disease and to disseminate advances in the clinical practice and basic science of pediatric nephrology. Currently has over 700 members, making it the primary representative of the pediatric nephrology community in North America.
American Society of Transplantation (AST)	4,000 transplant professionals dedicated to advancing the field of transplantation and improving patient care
Asian and Pacific Islander American Health Forum (APIAHF)	Nation's oldest and leading health policy organization working to advance the health and well-being of over 20 million Asian Americans, Native Hawaiians and Pacific Islanders across the U.S. and territories. Works to improve access to and quality of care for communities who are predominantly immigrant, many of whom are limited English proficient and may be new to the U.S. health care system or unfamiliar with private or public coverage.
Association of Black Cardiologists (ABC)	Non-profit organization founded in 1974 with 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. Dedicated to eliminating disparities related to cardiovascular disease for all people of color and adhere 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.
Beyond Flexner Alliance (BFA)	National movement focused on health equity and training health professionals as agents of more equitable health care. Promotes its social mission; programs; and performance of its graduates, faculty, and leadership in advancing health equity and addressing the health disparities of the society in which it exists.

Organization	Organization Description
Brown University (Brown)	Represents five academic researchers and clinicians at Brown University to concerned with the continued use of race-based algorithms in medicine.
California Pan-Ethnic Health Network (CPEHN)	Statewide, multicultural health advocacy organization dedicated to the elimination of health disparities for communities of color.
Center for Surgery and Public Health (CSPH)	Research division of the Department of Surgery at Brigham and Women's Hospital, focusing on surgical health services research. Since founding in 2005, CSPH has studied inequities in access, treatment, and outcomes related to surgical care delivery, including trauma, cancer, gynecological, and essential surgery
Charlene J. (Sharry) Langdale	Individual respondent.
City University of New York (CUNY) School of Medicine	Located in Northeastern U.S.; conducted a qualitative research project with participants who identify as Black, Indigenous, LatinX, and other people of color.
Equity, Research and Innovation Center at Yale University School of Medicine	Researcher, clinician, and public health policy leader committed to health equity.
Institute for Healing & Justice in Medicine (IHJM)	Organization of over 100 students, physicians, and researchers founded in early 2020 to prioritize equity and justice while reimagining clinical practice, education, and research. Serves as an interdisciplinary, centralized hub for social justice and community activism in medicine that can be appreciated by, contributed to, and accessible to people of all backgrounds.
Mass General Brigham (MGB)	Boston-based non-profit integrated health system, caring for 1.5 million patients annually.
Phyllis Chestang, MBA, PhD	Individual respondent.
Society of General Internal Medicine (SGIM)	Represent 3,000 general internists who provide clinical services and conduct research and teaching intended to achieve vision for a just system of care in which all people can achieve optimal health

APPENDIX C: BRIEF HISTORY OF CDSTS

Over the last 60 years, CDSTs have evolved in four distinct phases: 1) standalone decision support systems, 2) integrated systems, 3) standards-based systems, 4) and service models. Each phase has enhanced the level of sophistication of its predecessor (see Figure 3). There is greater interest in the more recent systems as the desire has grown for CDSTs that are web-based and integrated with EHRs to utilize the power of health informatics to transcend geography and reduce overhead costs.

The first CDSTs were *standalone systems*, where each tool only addressed one specific area of medicine, relying on manual inputs to make clinical recommendations. This approach came with an increased risk of missing data, inaccurate entry, and medical errors due to the absence of automated features. On the other hand, standalone systems inherently allowed the flexibilities that came with varied input and portability, while preserving clinical autonomy in treatment planning.

In 1967, *integrated systems* emerged as CDST developers integrated their tools with the earliest EHRs to eliminate some of the siloed characteristics of standalone systems.[139] Integrated systems allowed CDSTs to expand usability to other clinical domains, such as nursing, pharmacy, and respiratory therapy. This integrated approach leveraged data stored electronically, eliminating some of the vulnerabilities manual data entry posed, reducing medical errors because of features that proactively alert clinicians of important information (e.g., dangerous drug interactions.[140] Despite these advancements, integrated CDSTs had limited portability because they were part of the architecture of larger clinical health systems.[141] Updates, including new clinical guidelines, were also cumbersome within integrated tools because knowledge and coding are intertwined, meaning refinements require review of the entire system's source code.

In a push for enhanced portability of decision-support content, the medical community attempted to standardize CDSTs beginning in 1989. *Standardized systems* provided a consistent method for knowledge, storage, and modeling within sharing decision-support content.[142] But, when first developed, an overwhelming number of standardized CDSTs made it difficult for professional consumers (e.g., clinicians, hospital administrators) to choose the most appropriate system. Additionally, such systems were not dynamic and were constrained by a lack of standardized terminology and input, with the standard-writer predetermining content that was not easily adaptable to the needs of individual clinicians.

In the fourth and current phase, *service model* CDSTs separate clinical information systems from components of integrated systems and recombine them using a standard application programming interface (API).[143] These tools first emerged in 2004, offering the advantage of standardized terminology by requiring clinical systems to provide guidance on

[139] Middleton B, et al., *supra* note 46.
[140] Id.
[141] Id.
[142] Id.
[143] Id.

mapping their terms to the API to facilitate uniform communication across systems.[144] Though service models represent advancement and show promise, limitations remain. Of the two types of service model CDSTs, one standardizes terms before the clinical system processes the data and the other standardizes terminology before applying the CDST to the data. As a result, both service model CDST programs are limited because they look within the clinical system or the CDST at a given time, but not across both.

[144] Middleton B, et al., supra note 46.