



Continuing to Address Gaps in Care in Minority Patients with Valvular Heart Disease

Discussion Summary
and Recommendations

February 2023 Roundtable



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Executive Summary — February 2023

In February 2023, the Association of Black Cardiologists (ABC) convened an invitation-only roundtable titled, “Continuing to Address Gaps in Care in Minority Patients with Valvular Heart Disease.” The event, held in Washington, D.C., brought together a multi-disciplinary and diverse group of stakeholders committed to improving diagnosis, treatment, and outcomes for minority patients with valvular heart disease (VHD). The impetus for the convening was to follow-up from a February 2017 ABC-hosted roundtable during which attendees identified top barriers contributing to – and solutions to address – health disparities and poor outcomes for minority patients with VHD. Following that discussion, ABC issued a paper, “Addressing Disparities in Contemporary Care of the Minority Patient with Valvular Heart Disease Summary Recommendations.”

The goals of the February 2023 convening were to: review progress made since the 2017 recommendations were issued; discuss areas that require continued attention and action; uncover new barriers to address VHD health inequities; and make specific recommendations regarding ways to improve outcomes for minority patients with VHD. Over the course of the convening, participants were encouraged to recommend concrete actions that can be taken to address gaps in care for minority patients with VHD. Recommendations were made during the various discussion sessions as well as through a discussion worksheet on which participants enumerated any additional recommendations or priorities they wished to raise to ABC.

Pages 3-9 of this document present five priority actions that roundtable participants wish to see advanced in the near-term, along with the complete set of recommendations that were put forth during the February 2023 roundtable. The pages that follow the recommendations present a summary of the roundtable discussion. The recommendations are presented by sector: ABC, the federal government (further organized by subagency or branch of government), health plans/payors, industry, patient advocacy organizations, and providers and medical professional societies. The recommendations illustrate the importance of a collaborative, multi-stakeholder approach in addressing inequities and improving diagnosis and treatment of VHD in minority patients.

Please note that the recommendations are a summary from event discussions and discussion worksheets and do not imply endorsement from any of the event attendees other than the Association of Black Cardiologists.

Following the meeting, we conducted a follow-up survey among meeting participants to help further prioritize and determine the most important actions to be taken.



The following recommendations emerged as the top priority actions:

*Roundtable members urge the **ABC** to:*

- Send a letter to the Centers for Medicare and Medicaid Services (CMS) formally requesting reconsideration of the current Coverage with Evidence Development (CED) requirements for Trans Aortic Valve Replacement (TAVR), and within that correspondence, request a follow-up meeting with the agency to further discuss how the CED currently thwarts minority patient access to TAVR and should be retired.
- Meet with the Food and Drug Administration (FDA) to discuss how the agency should hold industry accountable for representativeness in clinical trials and how ensuring diversity in trials will advance equity in cardiology; as part of this effort, meet with the FDA Office of Minority Health and Health Equity.
- Continue to engage in education and outreach efforts with clinical, industry, and patient advocacy partners to boost awareness of VHD and appropriate treatments.

*Roundtable members urge the **federal government** to:*

- Improve access to care (not just insurance coverage but actual access to providers) so patients can get the diagnoses and treatment they need without barriers.
- Support local and national outreach and awareness efforts, including a range of providers (e.g., nurses, physicians, pharmacists, health educators, community health workers) to boost patient awareness of signs, symptoms, and treatment for VHD.

Complete Set of Roundtable Recommendations

ASSOCIATION OF BLACK CARDIOLOGISTS

- Meet with the National Heart, Lung, and Blood Institute (NHLBI), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute on Minority Health and Health Disparities (NMHD), and the National Institutes of Health (NIH) Director to discuss health inequities and disparities in VHD.
- Send a letter to CMS formally requesting reconsideration of CED requirements for TAVR, and within that correspondence, request a follow-up meeting with the agency to further discuss how the CED currently thwarts minority patient access to TAVR and should be retired.
- Meet with FDA to discuss how the agency should hold industry accountable for representativeness in clinical trials and how ensuring diversity in trials will advance equity in cardiology; as part of this effort, meet with the FDA Office of Minority Health and Health Equity.
- Meet with the U.S. Health and Human Services' Office of Minority Health to discuss an all-of-HHS approach to VHD in minority patients.



- Meet with the Agency for Healthcare Research and Quality (AHRQ) to discuss areas of research that the agency should pursue to help advance equity and address disparities in VHD.
- Urge Congress to add an enforcement mechanism to current FDA requirements mandating that clinical trial sponsors submit diversity action plans to the FDA.
- Continue to engage in education and outreach efforts with clinical, industry, and patient advocacy partners to boost awareness of VHD and appropriate treatments.
- Engage directly with primary care providers, primary care associations, and other groups (e.g., community health centers) to educate them about the equity issues associated with VHD among minority patients to increase screening, diagnosis, and treatment.
- Work with other cardiology societies to develop an accessible educational tool for non-cardiologists to help them think more regularly about VHD, particularly among their female and minority patients, and elevate it higher in their process of differential diagnosis (e.g., “Could it be VHD?”)

FEDERAL GOVERNMENT

GENERAL RECOMMENDATIONS

- Continue to leverage a whole-of-government approach to addressing social determinants of health (SDOH) to help dismantle long-standing health inequities and improve quality of care and health outcomes for minority patients; such efforts should include advancing training regarding implicit bias and how it impacts quality of care and outcomes for minority patients.
- Support local and national outreach and awareness efforts, including a range of providers (e.g., nurses, physicians, pharmacists, health educators, community health workers) to boost patient awareness of signs, symptoms, and treatment options for VHD.
- Improve access to care (not just insurance coverage but actual access to providers) so patients can get appropriate and timely diagnoses and treatment.
- Acknowledge that systemic racism contributes directly to SDOH, which in-turn undermines health and well-being among individuals and communities of color.
- Create a pilot VHD screening program involving primary care providers, family physicians, and advanced practice nurses to ensure that people with risk factors for VHD are screened and anyone with VHD learns of their condition and can seek care/treatment.
- Break down data silos across agencies to improve shared decision-making and overall patient care.
- Establish a pilot patient navigator program that specifically supports minority and underserved VHD patients from diagnosis through treatment so more of these patients receive standard of care for VHD.



CMS

- Before the end of 2023, retire the Coverage with Evidence Development (CED) on TAVR and issue an affirmative National Coverage Determination (NCD) according to its FDA-approved indications, as existing data demonstrates that there is no longer a relationship between volume and health outcomes.
- Implement high-impact quality measures that help further identify gaps in VHD for minority patients and better understand overall incidence and prevalence rates in minority communities.
- Test and support models that encourage the integration and coordination of primary and specialty care to assist in VHD detection, promote the adoption of innovative technologies, and stimulate participation of providers that care for underserved patient populations.
- Create payment policies and programs that will advance efforts to diagnose VHD via echocardiogram/Artificial Intelligence (AI) and improve referral to cardiac follow-up care for all individuals diagnosed with VHD.
- Provide payment incentives to make diagnostic tools more widely available in minority communities.
- Increase payments to providers who treat traditionally underserved patients and communities, recognizing additional resources are necessary to address health disparities and access issues.
- Hold providers accountable for ensuring that minority and female patients receive the appropriate standard of care in VHD.
- Cover and reimburse echocardiograms for screening for VHD without a requirement of prior authorization or demonstration of “medical necessity.”

CONGRESS

- Mandate changes for clinical trial data collection methodology to promote data quality and trial integrity; as part of this effort, add an enforcement mechanism (e.g., financial penalties) to current FDA requirements mandating that clinical trial sponsors submit diversity action plans to the FDA.
- Enact legislation that provides incentives to industry to develop medical products for VHD and rewards nationally representative demographic trials (e.g., 1983 Orphan Drug Act).
- Consider Medicare and Medicaid expansion reforms such as lowering the age of eligibility, creating a Medicare buy-in program, and offering robust financial incentives to non-Medicaid expansion states to help reduce coverage gaps.
- Provide competitive grants to improve and expand a diverse cardiovascular clinical workforce.
- If CMS does not take action to retire the CED policy for TAVR, enact a statute that prohibits the agency from continuing the policy and requires the agency to provide coverage and reimbursement for TAVR without restrictions.



- Increase the supply of cardiology providers by increasing opportunities throughout the education pipeline, especially by funding an increasing number of residency slots.

FDA

- Hold industry sponsors accountable in a meaningful way to have clinical trial populations that reflect/match the population intended to use the treatment/intervention.
- Hold the Center for Devices and Radiological Health (CDRH) accountable for achieving the “Advance Health Equity” strategic priority outlined in its 2022-2025 plan,¹ which states, among proposed strategies and actions, that CDRH will “partner with patients, health care providers, industry, and payers to advance solutions that promote equity along the total product life cycle, including access to care.”

NIH & RESEARCH COMMUNITY

- The NHLBI should revisit and provide an annual update on its “2019 Priorities for Patient-Centered Research in Valvular Heart Disease: A Report from the National Heart, Lung, and Blood Institute Working Group” published in the April 2020 *Journal of the American Heart Association* and update stakeholders on the status regarding recommendations.
- Review specialty society and USPSTF guidelines on echocardiogram screening/detection for high-risk and underserved communities.
- Sponsor demonstration projects that support clinical trial enrollment diversity and VHD diagnosis in minority communities.
- Ensure that patients are at the table and engaged throughout the research process, including the end-points of interest to all parties involved.
- Consider ways that real-world evidence can be collected to support and advance understanding and treatment of VHD.
- Enhance the VHD data infrastructure, including the collection of SDOH data, to bolster evidence-based policies and practices aimed at reducing health disparities.
- Support training programs such as fellowships for clinicians of color so there is a more diverse network of providers available to perform VHD procedures across the country.

HEALTH PLAN PAYORS (GOVERNMENT AND COMMERCIAL)

- Limit restrictive prior authorization practices of cardiac tests and treatments that delay timely access to care.
- Prioritize “value over volume” by adjusting payment models to support whole-person care to allow greater alignment of incentives regarding diagnosis and treatment
- Expand coverage of VHD providers and hospitals to reduce inequities in surgical care.
- Remove payment barriers that hurt providers located in underserved and hard-to-reach communities.

¹ Food and Drug Administration. Center for Devices and Radiological Health. 2022-2025 Strategic Priorities. <https://www.fda.gov/media/155888/download>



- Establish a specific quality measure tied to ensuring that underrepresented patients are screened and appropriately treated for VHD (e.g., TAVR).
- Ensure that TAVR is covered and paid for all patients for whom it is clinically indicated.

INDUSTRY

- Convene C-suite executives to address health equity and existing challenges, such as TAVR underutilization among minority patients and low minority representation in clinical trials.
- Make the business case for diversity, equity, and inclusion; as part of this effort, illustrate the positive economics of ensuring that all patients – particularly minority patients – who have VHD are diagnosed and treated in a timely and state-of-the-art manner.
- Support innovation of screening technologies and other diagnostic tools that assist with prevention and diagnosis of vascular heart disease.
- Develop and disseminate direct-to-patient marketing campaigns featuring targeted interventions that encourage VHD prevention and diagnosis.
- Explore medical product design strategies that deliver products at the lowest cost to the patient without compromising quality standards.
- Innovate programs that promote clinical efficiencies, enhance diagnostic accuracy upstream, reduce workflow delays, and allow for more individuals that meet indications for therapy to access therapy in a timely fashion.
- Provide funding/sponsor fellows to expand the network of interventional cardiologists to ensure that all hospitals can provide access to valvular heart disease treatment strategies.
- Hold academic institutions accountable for representative enrollment in clinical trials by including diversity among the factors that companies use to assess a clinical site for a study.
- Help fund grassroots efforts that aim to address racial health disparities; as part of this effort, target resources to organizations that emphasize elevating Black community members who are addressing racial disparities.
- Leverage technology as an enabler of clinical trial diversity strategies in biopharma and medical device innovation.
- Engage in collaborations with other companies to address diversity in clinical trials and share lessons learned.
- Reframe issues of diversity, equity, and inclusion as “emerging markets” to illustrate the economic (not just moral) value of addressing SDOH.

PATIENT ADVOCACY ORGANIZATIONS

- Actively help to involve constituents in clinical research so they can contribute to trial design and diversify participation/enrollment.
- Highlight and spotlight patient’s stories for awareness and advocacy efforts, specifically using examples that underscore gender/sex disparities in VHD.



- Hold government agencies, payors, industry, and medical professional societies accountable to the VHD health equity objectives to which they have made a commitment by asking for regular report-outs on actions taken and the impact made.
- Empower patients with health information and resources to strengthen informed decision-making related to VHD, including helping them learn about the signs and symptoms of VHD and the range of treatments available, so they can engage in self-advocacy.
- Provide educational resources and other forms of assistance to help patients seek and receive VHD care from high-quality proceduralists and surgeons in addition to treatment centers.
- Partner with heads of industry to produce and distribute VHD patient education resources.
- Help fill data gaps that specifically address prevalence, cost barriers, and economic value of TAVR.
- Increase education on gender disparities that exist within VHD and help dismantle stigmas/stereotypes that portray heart disease as a “man’s disease.”
- Further leverage annual Heart Valve Disease Awareness Day to reach more individuals, families, and clinicians to improve diagnosis and treatment, with a particular focus on diverse individuals and communities.
- Engage in efforts to ensure diversity and inclusion among volunteer advocates and staff so that patient organizations are more representative of the communities they seek to serve.
- Help ensure that prospective patients can speak to a TAVR patient who has had a similar lived experience; as part of this effort, continue to work to diversify the participants in patient-to-patient initiatives such as, but not limited to, the TAVR Visiting Program.

PROVIDERS AND MEDICAL PROFESSIONAL SOCIETIES

- Utilize state-of-the-art screening tools and better technologies to reduce misdiagnosis and underdiagnosis of VHD.
- Help increase awareness of VHD among non-cardiologists and the vital importance of cardiovascular screenings across the lifespan.
- Support the development and facilitation of community-based VHD screening programs to meet patients where they are and support efforts to ensure follow-up for treatment.
- Design a more streamlined, patient-friendly approach to imaging so minority patients, in particular, can minimize the amount of time they need to take away from work, school, family, etc.; as part of this effort, be mindful of the disproportionate negative impact of lost time/wages disproportionately on patients of color and challenging socio-economic status when they have to seek testing.
- Train providers to adopt “upstream” approaches to emphasize risk factor modification and address impacts of SDOH on whole-person care; ensure medical education and residency and fellowship programs include teaching about health equity.



- Recruit and retain a diverse and inclusive cardiovascular clinical workforce through workforce development programs, mentorship opportunities, and continuing education in the field of cardiology.
- Strengthen the next generation of clinicians by incorporating DEI-focused training programs into medical education, including implicit bias training.
- Employ a multi-disciplinary care approach that connects patients to patient navigators, social workers, community resources, pharmacists, and other resources.
- Engage with patients and their family members where they “live, play, and pray” to help build trusted provider-patient relationships.
- Emphasize and help address the impact of systemic racism on patient care experiences and outcomes.
- Provide patient-friendly educational resources to promote health literacy within VHD.
- Ensure that medical journals/publications require that study populations are diverse as part of their publication criteria.
- Engage more primary care providers and other non-cardiologists in recognizing the importance of diagnosing and treating VHD; as part of this effort, ensure clinicians understand the risk factors and common accompanying conditions (e.g., diabetes) with VHD.
- Build a trusted referral network of high-volume hospitals to help reduce access inequities around VHD surgical care.



Introduction

Valvular heart disease (VHD) is a degenerative condition that is characterized by improper heart valve functioning, either due to stenosis (narrowing of the heart valve) or regurgitation (leaky heart valve). Nearly 2.5% of the U.S. population has VHD, with a higher prevalence in older adults.² Left untreated, VHD can result in grave health complications such as heart failure, stroke, and sudden death. According to the Agency for Healthcare Research and Quality, heart failure is the second most common cause of 30-day adult hospital readmissions.³ Aortic stenosis (AS), the second most common VHD in the United States,⁴ shares many of the same risk factors as atherosclerosis, such as older age, hypertension, tobacco use, and male sex.⁵ Of particular concern is that underrepresented racial and ethnic groups “relative to white patients possess higher rates of traditional risk factors, such as congestive heart failure, chronic kidney disease, smoking, hypertension, obesity, and diabetes mellitus.”⁶

Despite having a higher prevalence of traditional risk factors for AS, underrepresented racial and ethnic groups experience a “paradoxically lower prevalence or incidence of AS relative to white subjects,” which can likely be attributed to underdiagnosis.^{7,8} While the prognosis for severe, symptomatic AS is generally poor, most studies show that the average life expectancy is 1-3 years and a 50% mortality risk for symptomatic patients who do not receive treatment compared to patients who receive aortic valve replacement experiencing “significantly better survival at 1 and 3 years.”⁹

The emergence of minimally invasive transcatheter procedures, such as transcatheter aortic valve replacement (TAVR) and transcatheter mitral valve repair (TMVR), indeed has been transformative to VHD care and outcomes. TAVR has been proven as a safe and effective treatment option across all AS patient cohorts, including those who are deemed as intermediate-

²Centers for Disease Control and Prevention (CDC). Valvular Heart Disease.

https://www.cdc.gov/heartdisease/valvular_disease.htm

³Weiss AJ (IBM Watson Health), Jiang HJ (AHRQ). Overview of Clinical Conditions With Frequent and Costly Hospital Readmissions by Payer, 2018. HCUP Statistical Brief #278. July 2021. Agency for Healthcare Research and Quality, Rockville, MD. www.hcup-us.ahrq.gov/reports/statbriefs/sb278-Conditions-Frequent-Readmissions-By-Payer-2018.pdf.

⁴Hollenberg SM. Valvular Heart Disease in Adults: Etiologies, Classification, and Diagnosis. *FP Essent.* 2017;457:11-16.

⁵Wilson JB, Jackson LR 2nd, Ugowe FE, et al. Racial and Ethnic Differences in Treatment and Outcomes of Severe Aortic Stenosis: A Review. *JACC Cardiovasc Interv.* 2020;13(2):149-156. doi:10.1016/j.jcin.2019.08.056

⁶ Ibid.

⁷ Ibid.

⁸ Parikh PB, Kort S. Racial and Ethnic Disparities in Aortic Stenosis. *J Am Heart Assoc.* 2022;11(24):e028131. doi:10.1161/JAHA.122.028131

⁹ Ibid.

and low-risk.^{10,11} TAVR has been especially critical to reducing morbidity and mortality for patients who are unable to undergo invasive surgery or are deemed high-risk.¹² However, not all patients are benefitting equally from the value of this technology. Historically, underrepresented racial and ethnic minority patients with severe AS have had “lower rates of both surgical and transcatheter aortic valve replacement and experience more post-surgical complications, including bleeding, worsening heart failure, and rehospitalization.”¹³ As a result, minority patients with severe AS often experience “an increased risk of morbidity and mortality, relative to white patients.”¹⁴ Data from the Society of Thoracic Surgeons (STS)–American College of Cardiology (ACC) Trans-catheter Valve Therapy Registry (STS-ACC TVT Registry) further demonstrates significant racial and ethnic disparities in the undertreatment of AS.¹⁵

“The past decade has seen major breakthroughs in the diagnosis and treatment of valvular heart disease (VHD)...transcatheter interventions for valve repair and replacement have changed the landscape of treatment options, especially for high-risk patients. However, there is mounting evidence that inequitable access to health care has systematically prevented racial and ethnic minorities from fully benefiting from these advancements...There are enormous health care disparities across racial and ethnic groups in the utilization of transcatheter aortic valve replacement (TAVR) and other structural heart interventions.”¹⁶

- Lamprea-Montealegre et al., *Journal of the American College of Cardiology* (2021)

The persistent underutilization of TAVR among minority patients remains a significant concern among clinicians, researchers, industry, and patient advocates and has prompted a clarion call to uncover the drivers of VHD disparities within minority communities, understand their interplay, and to identify actions to improve access, advance equity, and address disparities.

¹⁰ Rogers T, Thourani VH, Waksman R. Transcatheter Aortic Valve Replacement in Intermediate- and Low-Risk Patients. *J Am Heart Assoc.* 2018;7(10):e007147. Published 2018 May 12. doi:10.1161/JAHA.117.007147

¹¹ Leon MB, Mack MJ, Hahn RT, et al. Outcomes 2 Years After Transcatheter Aortic Valve Replacement in Patients at Low Surgical Risk. *J Am Coll Cardiol.* 2021;77(9):1149-1161. doi:10.1016/j.jacc.2020.12.052

¹² Ibid.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol.* 2020;76(21):2492-2516. doi:10.1016/j.jacc.2020.09.595

¹⁶ Lamprea-Montealegre Julio A. et al. Valvular Heart Disease in Relation to Race and Ethnicity. *J Am Coll Cardiol.* 2021; 78(24):L 2493-2504. Doi:10.1016/j.jacc.2021.04.109



Roundtable Overview

As the leading national organization committed to advancing equity and preventing and addressing health disparities within cardiovascular health, on February 24, 2023, the Association of Black Cardiologists (ABC) held its second invitation-only roundtable symposium on addressing disparities within VHD. The convening, “Continuing to Address Gaps in Care in Minority Patients with Valvular Heart Disease” was attended by an interdisciplinary group of stakeholders, including government officials, clinicians, researchers, members of national medical and public health associations, industry representatives, and patient advocates. The goal of the meeting was to identify the challenges and barriers that prevent minority patients from access to contemporary valvular and non-valvular heart disease therapies, opportunities to improve clinical outcomes of minority patients undergoing treatment for valvular heart disease, and enumerate the action steps that the federal government, health plans/payors, industry, clinicians, medical professional organizations, and patient advocacy groups can take to address health disparities and advance equity within VHD.

Roundtable participants, through a series of panel presentations and facilitated discussion, explored a range of topics, including a review of the progress and developments since the 2017 roundtable; clinical shortcomings in diagnosis and treatment; the “business case” for health equity; federal efforts to reduce health care disparities; and the need for greater diversity in clinical trials. Panelists provided clinical, industry, government, and patient perspectives regarding the challenges in addressing care gaps for minority patients with VHD. Concluding the convening was a group discussion to develop a set of recommendations to help close care gaps and improve access and outcomes for minority patients with VHD.

Where We Were: ABC 2017 Roundtable History and Recommendations

In June 2017, the ABC convened its first roundtable discussion on disparities in VHD. At the time, there was a still-evolving technological innovation, TAVR, which was creating an important practice change in VHD and the challenge – if the process was not managed correctly – was that it had the potential of widening the gap in care for minority patients. At that time, roundtable participants identified several barriers to care, including a lack of awareness about both the disease state and available treatment options like TAVR; significant research gaps; and limited minority participation in clinical trials.

Following the 2017 discussion, ABC proposed a set of recommendations aimed at increasing disease state and treatment awareness of VHD. Suggested efforts included, but were not limited to, conducting pre-TAVR or surgery surveys to address patient concerns and promote shared decision-making; utilizing health data sources (e.g. public health surveillance data, electronic health records, and insurance claim data) to better understand reasons for VHD treatment hesitancy and refusal; developing a diverse task force to address disparities in VHD care; and



building an effective national campaign to increase education and awareness around VHD.¹⁷ Further, the 2017 roundtable discussion and subsequent recommendations underscored the need to address awareness gaps among minority patients and their family members regarding available and clinically appropriate VHD treatment options.

Where We Are: Inequities In VHD Diagnosis and Treatment Persist

“Advances in valvular heart disease are just extraordinary. [Yet] availability and adaption of such advances are thwarted by failures of prevention, diagnostic evaluation, and adoption of state-of-the-art treatment.”

- Roundtable Participant

For more than 10 years, ABC has played an integral role in helping advance research regarding the underutilization of TAVR among people of color. ABC has supported the development of a significant body of peer-reviewed evidence (see Appendix) that provides important insights regarding the myriad reasons why TAVR is underutilized among patients of color who have AS. ABC-supported studies found that despite groundbreaking clinical advancements in cardiovascular care and well-documented evidence regarding significant racial health disparities within VHD, minority patients continue to face a higher disease burden of vascular heart disease risk factors and, therefore, higher mortality and morbidity.^{18,19,20}

Of serious and ongoing concern is that the percentage of patients receiving TAVR, in essence, has remained unchanged since the last ABC roundtable on the topic and since the STS-ACC TVT Registry has collected data. According to the “State of TAVR in the United States” published by Carroll et al. in November 2020 in the *Journal of the American College of Cardiology*, 4.04% of patients receiving TAVR in 2019 were Black, with an overall rate of 3.98% for the period 2011 through 2019.²¹ The authors note that while “Black patients receiving TAVR have increased from

¹⁷Association of Black Cardiologists. Addressing Disparities in Contemporary Care of the Minority Patient with Valvular Heart Disease Summary Recommendations. June 2017. https://abcario.org/wp-content/uploads/2017/06/ABC-Summary-Recommendations_Addressing-Disparities-in-Valvular-Heart-Disease.pdf

¹⁸ Lamprea-Montealegre JA, Oyetunji S, Bagur R, Otto CM. Valvular Heart Disease in Relation to Race and Ethnicity: JACC Focus Seminar 4/9. *J Am Coll Cardiol*. 2021;78(24):2493-2504. doi:10.1016/j.jacc.2021.04.109

¹⁹ See Appendix, Peer Reviewed Research on Underrepresented Minority Patients with Aortic Stenosis.

²⁰ Lindman BR, Arnold SV, Bagur R, et al. Priorities for Patient-Centered Research in Valvular Heart Disease: A Report From the National Heart, Lung, and Blood Institute Working Group. *J Am Heart Assoc*. 2020;9(9):e015975. doi:10.1161/JAHA.119.015975

²¹ Carroll, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement.



504 during the early TAVR period to 2,948 in 2019...there has been no change in only 4% of all patients receiving TAVR being Black.”²²

| Year | ≤2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | Overall |
|---------------------------------|-------|------|------|------|------|------|------|---------|
| Rate TAVR Black Patients | 3.67 | 3.94 | 3.79 | 3.91 | 3.98 | 4.13 | 4.04 | 3.98 |

Source: STS-ACC TVT Registry

Carroll et al. note that the STS-ACC TVT Registry “does not have a means to study underlying issues that may account for health care disparities versus disease prevalence. But the registry can monitor the impact of efforts to increase access and reduce disparities.”²³

Causes of and Contributors to Health Disparities within VHD

The causes of VHD disparities are multifaceted and include, but are not limited to, institutional racism, historical mistrust in the U.S. health care system, underutilization of available interventions, the impact of social determinants of health (SDOH) on diagnosis and treatment, inequitable federal coverage and reimbursement policies, and lack of diversity within clinical trials.

“Race-based disparity may be the most common cause of death among Black men and women under age 65 years of age. Cardiovascular disease accounts for more than one-third of the mortality difference between Black and White individuals in the US and remains the number 1 cause of death in the US ... Despite the effectiveness of cardiovascular interventions, adults from racial and ethnic minority groups and those with low incomes are less likely to receive these interventions and are more likely to have poorer outcomes after undergoing these therapies.”²⁴

- Glance et al., JAMA Network Open (2022)

²² Ibid.

²³ Ibid.

²⁴ Glance LG, Joynt Maddox KE, Mazzeffi M, et al. Racial and Ethnic Disparities in Access to Minimally Invasive Mitral Valve Surgery. JAMA Netw Open. 2022;5(12):e2247968. doi:10.1001/jamanetworkopen.2022.47968



Historical Mistrust and Structural Racism in the U.S. Health Care System

From its advent, the American health care system has perpetuated an inequitable system of care that continues to be felt today in minority and underserved communities. Longstanding laws and policies, institutional practices, racial biases, and systemic racism have unjustly impeded access to high-quality, affordable health care for tens of millions of minority Americans. The pervasiveness of structural racism in the United States serves as a major determinant of adverse health care outcomes and plays a significant role in the cause of enduring disparities.²⁵ The American Heart Association has “recognized structural racism as a fundamental cause of poor health and disparities in cardiovascular disease.”²⁶

Illustrating the structural nature of disparities and inequities, Laurent et al. found that “Black patients with severe aortic stenosis are less likely than White patients to undergo aortic valve replacement.”²⁷ Minority and low-income adult patients “who do undergo surgical revascularization or heart valve surgery are more likely to receive care from lower quality, lower volume hospitals and surgeons, and have higher periprocedural mortality.”²⁸ Studies have found that TAVR centers have been concentrated “predominately in metropolitan areas that [take] care of socioeconomically more advantaged patients” and that in “areas with higher proportions of Black, Hispanic, and socioeconomically disadvantaged patients had lower age-adjusted rates of TAVR, suggesting the presence of inequities in access to this procedure.”²⁹ Federal value-based payment programs designed to deter hospital readmissions have also reinforced inequitable health care delivery. Hospitals that serve a large population of minority patients have been some of the hardest hit by CMS financial penalties, highlighting the ongoing need to reform existing incentive structures and “create, validate, and apply better measures of equitable access to important procedures and technologies.”³⁰ Further, underutilization of available VHD surgical and transcatheter treatments emboldens existing access and resource inequities that are deeply embedded in the patient, provider, and system levels.³¹

Further, historical mistreatment of minority patients by the medical community has contributed to a lasting legacy of mistrust and, in many cases, a separate and drastically unequal health care

²⁵Lamprea-Montealegre et al. Valvular Heart Disease in Relation to Race and Ethnicity: JACC Focus Seminar 4/9.

²⁶Churchwell K, Elkind MSV, Benjamin RM, et al. Call to Action: Structural Racism as a Fundamental Driver of Health Disparities: A Presidential Advisory From the American Heart Association. *Circulation*. 2020;142(24):e454-e468. doi:10.1161/CIR.0000000000000936

²⁷Glance et al. Racial and Ethnic Disparities in Access to Minimally Invasive Mitral Valve Surgery.

²⁸Ibid.

²⁹ Nathan AS, Reddy KP, Yang L, et al. Characteristics of Clinical Trial Sites for Novel Transcatheter Mitral and Tricuspid Valvular Therapies. *JAMA Cardiol*. 2023;8(2):120-128. doi:10.1001/jamacardio.2022.4457

³⁰ Glance et al. Racial and Ethnic Disparities in Access to Minimally Invasive Mitral Valve Surgery.

³¹³¹Lamprea-Montealegre et al. Valvular Heart Disease in Relation to Race and Ethnicity: JACC Focus Seminar 4/9.



system in the United States. Distrust of the clinical research system, racism, discrimination, and other drivers of inequity are inextricably linked to adverse cardiovascular health outcomes among minority and underserved individuals.³² This deep-rooted history and minority patients' continued reluctance to engage with a health care system that is still rife with inequalities must be considered when addressing and responding to VHD disparities.

Underutilization of TAVR and Other Structural Heart Interventions

Despite the widespread commercialization and clinical availability of VHD treatments, there is persistent underutilization of TAVR and other lifesaving structural heart interventions among minority patients.³³ According to the STS-ACC TVT Registry, only 7% of all TAVR procedures performed between 2011 through 2019 were among racial and ethnic minority groups.³⁴ Despite accounting for nearly 20% of the U.S. population 65 and older, Black and Hispanic patients have disproportionately received TAVR procedures far less often than their White counterparts.^{35,36} Specifically, TVT Registry data reveal that from 2011-2019, of those receiving TAVR, 3.98% of patients were Black, 4.7% were Hispanic, and 92.98% were White.³⁷

“...We have essentially leveraged [TAVR] technology to improve outcomes. What is missing from this narrative is that the benefits from this therapeutic innovation are varied across the population, depending on gender, race, and socioeconomic status ...We must work diligently to remove barriers to receiving these innovative treatments...”

- Roundtable Participant

³² Javed Z, Haisum Maqsood M, Yahya T, et al. Race, Racism, and Cardiovascular Health: Applying a Social Determinants of Health Framework to Racial/Ethnic Disparities in Cardiovascular Disease. *Circ Cardiovasc Qual Outcomes*. 2022;15(1):e007917. doi:10.1161/CIRCOUTCOMES.121.007917

³³ Wilson JB, Jackson LR 2nd, Ugowe FE, et al. Racial and Ethnic Differences in Treatment and Outcomes of Severe Aortic Stenosis: A Review. *JACC Cardiovasc Interv*. 2020;13(2):149-156. doi:10.1016/j.jcin.2019.08.056

³⁴ Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol*. 2020;76(21):2492-2516. doi:10.1016/j.jacc.2020.09.595

³⁵ Administration for Community Living (ACL). 2020 Profile of Older Americans. May 2021. https://acl.gov/sites/default/files/aging%20and%20Disability%20In%20America/2020Profileolderamericans.final_.pdf

³⁶ Carroll JD, Mack MJ, Vemulapalli S, et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement. *J Am Coll Cardiol*. 2020;76(21):2492-2516. doi:10.1016/j.jacc.2020.09.595

³⁷ Wilson et al. Racial and Ethnic Differences in Treatment and Outcomes of Severe Aortic Stenosis: A Review.



While the utilization gap of TAVR has narrowed marginally among Black and Hispanic patients since 2013, treatment rates for AS remain alarmingly low. Underlying factors that may contribute to poor TAVR utilization rates among minority individuals include limited access to TAVR performing institutions and providers, participants' age, insurance status, and socioeconomic status.³⁸ Wilson et al. note that "The reasons for this difference in TAVR receipt are likely multifactorial, with a complex interplay of socioeconomic, cultural, and patient- and provider-centric factors." Specifically, patients' mistrust of physicians and the health system, patients' denial or misunderstanding of the grave risk associated with undertreated AS, and the lack of access to care and qualified services all likely play a role in differences in the receipt of TAVR procedures."³⁹

The disparate use of cardiovascular interventions like TAVR raises critical questions regarding access to care, provision of care, and the influence of social determinants of health (SDOH), which include "economic stability, access to quality education, social and community context, and access to quality health care."⁴⁰ Lamprea-Montealegre et al. note that "Finding solutions to overcome these disparities must be an integral component of the quest to improve cardiovascular health."⁴¹

Similar observations also have been documented for other structural heart interventions, including, but not limited to, surgical aortic valve replacement (SAVR), tricuspid valve surgery, transcatheter mitral valve repair (TMVR), left atrial appendage closure, and transcatheter edge-to-edge repair (TEER).^{42,43,44} For instance, Lamprea-Montealegre et al. reported that the majority of patients (approximately 60%) who underwent tricuspid valve surgery were White, while an estimated 10% were Black patients and 6% were Hispanic patients. In a study titled "Racial Disparities in Access to High-Volume Mitral Valve Transcatheter Edge-to-Edge Repair Centers" published by Steitieh et al. in the *Journal of the Society for Cardiovascular Angiography & Interventions* (JSCAI) in July 2022, revealed that Black and Hispanic patients accessed TEER at

³⁸Oyenubi O, Benjamin P, Chan M, et al. Racial Inequalities in the Use Of Transcatheter Aortic Valve Replacement Among Us Adults with Aortic Stenosis: A Blinder-Oaxaca Decomposition Analysis. *J Am Coll Cardiol.* 2022 Mar, 79 (9_Supplement) 651. [https://doi.org/10.1016/S0735-1097\(22\)01642-4](https://doi.org/10.1016/S0735-1097(22)01642-4)

³⁹ Wilson et al. Racial and Ethnic Differences in Treatment and Outcomes of Severe Aortic Stenosis: A Review.

⁴⁰Lamprea-Montealegre et al. Valvular Heart Disease in Relation to Race and Ethnicity: JACC Focus Seminar 4/9.

⁴¹Ibid.

⁴² Ibid.

⁴³Alkhouli M, Alqahtani F, Holmes DR, Berzingi C. Racial Disparities in the Utilization and Outcomes of Structural Heart Disease Interventions in the United States. *J Am Heart Assoc.* 2019;8(15):e012125. doi:10.1161/JAHA.119.012125

⁴⁴ Steitieh D, Zaidi A, Xu S, et al. Racial Disparities in Access to High-Volume Mitral Valve Transcatheter Edge-to-Edge Repair Centers. *JSCAI.* 2022;1(5):100398-100398. doi:<https://doi.org/10.1016/j.jscai.2022.100398>



lower rates when compared to White patients.⁴⁵ In a follow-up interview, Steitieh identified socioeconomic factors, “including lower rates of preventive healthcare in minority groups that result in fewer referrals for TEER,” lack of availability of specialized structural heart centers, and potential reluctance to undergo invasive or surgical procedures as potential contributors to these access disparities.”⁴⁶ While presently there is a paucity of data specifically addressing racial and ethnic disparities in other treatment areas outside of TAVR, it is obvious that access issues in structural heart care are pervasive among minority patients with VHD. This emphasizes the critical need to ensure affordability of – and accessibility to – all existing and new and novel valvular therapies, once FDA-approved.

Medicare Coverage Challenges for TAVR

An analysis of Medicare data from 2003 estimated that the total annual cost of medically managed severe, symptomatic AS is between \$600 million and \$1.3 billion per year, representing a substantial financial burden to the health care system.⁴⁷ As the predominant insurer for more than 65 million Americans, Medicare plays an indispensable role in ensuring that quality and affordable care is within reach for VHD patients. In 2012, the Centers for Medicare and Medicaid Services (CMS) issued a National Coverage Determination (NCD) providing Medicare reimbursement for TAVR under a Coverage with Evidence Development (CED) policy, which was updated in 2019. Medicare reimbursement is provided for FDA-approved TAVR only if the provider submits patient-level data to a national registry. Currently, according to the STS-ACC TVT Registry, at the end of August 2020, there were 715 sites in the United States providing TAVR and the procedure is available in all 50 states.⁴⁸

In order to be eligible for TAVR Medicare coverage, participating hospitals and centers must meet procedural volume requirements specified in the NCD with CED. With the original NCD with CED, the procedural volume requirements were used as a surrogate for quality of care.⁴⁹ After more than a decade of extensive evidence development, it is clear that volume requirements for TAVR are both outdated and arbitrary. The Association of Black Cardiologists, in partnership with the Alliance for Aging Research, along with other leading national patient advocacy groups, has long warned how the continuation of the CED requirement heightens disparities and threatens TAVR

⁴⁵ Ibid.

⁴⁶ *Black and Hispanic Patients Not Accessing High-Volume TEER Center*. TCTMD. July 2022.

<https://www.tctmd.com/news/black-and-hispanic-patients-not-accessing-high-volume-teer-centers>

⁴⁷ Wilson et al. Racial and Ethnic Differences in Treatment and Outcomes of Severe Aortic Stenosis: A Review.

⁴⁸ Carroll et al. STS-ACC TVT Registry of Transcatheter Aortic Valve Replacement

⁴⁹ Alliance for Aging Research. Comments submitted to CMS Administrator Seema Verma on Proposed decision on Medicare’s National Coverage Decision (NCD) for transcatheter aortic valve replacement (TAVR) (CAG-00430R). April 2019. <https://www.agingresearch.org/wp-content/uploads/2018/07/CMS-Proposed-TAVR-Decision-Response-4-25-19.pdf>



accessibility for racial and ethnic minorities, women, and rural beneficiary populations.⁵⁰ Retaining these onerous requirements restricts access to care, risks more TAVR Centers shutting their doors, prevents the opening of new ones, and drives differences in treatment outcomes, as “patient proximity to hospitals impacts facility choice even when reported health outcomes differ significantly.”⁵¹

TAVR health outcomes have been found to be “excellent in both high-and-low volume facilities indicating that procedural volume may not be an effective indicator of quality.”⁵² By maintaining the NCD with CED for TAVR, CMS gravely ignores well-established clinical benefits and, by doing so, inadvertently restricts access to lifesaving treatment for patients in need. As the largest health care payer in the United States, CMS serves as a critical steward for advancing and implementing the Biden-Harris Administration’s promise of health equity and can play an integral role in reducing VHD inequities by retiring the TAVR CED and issuing an affirmative patient-centric NCD that prioritizes value over volume.

Impact of Social Determinants of Health on Diagnosis and Treatment

Social determinants of health (SDOH) play a significant role in the development of valvular heart disease risk factors, morbidity, and mortality among minority patients.⁵³ For example, Black adults experience higher rates of hypertension and obesity and are two times more likely to die of heart disease than their White counterparts.⁵⁴ Further, factors such as income, education levels, and access to health care may deter minority patients exhibiting symptoms of vascular heart disease from seeking medical care, leading to the consequential delay of diagnosis and treatment. Glance et al. highlight that “individuals from racial and ethnic minority groups face social and structural barriers to preventive health resources, and excessive activation of the stress response caused by safety, socioeconomic concerns, and racial discrimination, which lead to worsening health over time—sometimes described as ‘weathering.’”⁵⁵

Of serious concern is that SDOH also have an adverse impact on the screening, diagnosis, and treatment of VHD among minority patients. Primary care is often the first point of contact for patients seeking medical attention and is vital to both early detection and management of VHD. Edelman and Thourani note that “barriers of access to primary health care reduce the

⁵⁰ Ibid.

⁵¹ Ibid.

⁵² de Biasi AR, Paul S, Nasar A, Girardi LN, Salemi A. National Analysis of Short-Term Outcomes and Volume-Outcome Relationships for Transcatheter Aortic Valve Replacement in the Era of Commercialization. *Cardiology*. 2016;133(1):58-68. doi:10.1159/000440694

⁵³ Powell-Wiley TM, Baumer Y, Baah FO, et al. Social Determinants of Cardiovascular Disease. *Circ Res*. 2022;130(5):782-799. doi:10.1161/CIRCRESAHA.121.319811

⁵⁴ Centers for Disease Control and Prevention (CDC). Racial and Ethnic Disparities in Heart Disease. April 2019. <https://stacks.cdc.gov/view/cdc/77732>

⁵⁵ Laurent Glance et al. Racial and Ethnic Disparities in Access to Minimally Invasive Mitral Valve Surgery.



opportunity for patients to have valvular disease diagnosed before the development of heart failure.”⁵⁶ Barriers to access, including lack of transportation and limited or no paid time off, have detrimental effects across the care continuum. According to Lamprea-Montealegre et al., “Even after echocardiographic diagnosis of severe AS, Black patients had over four-fold declining AVR, being lost to follow-up, and not being referred to cardiology.”⁵⁷ The authors recognize that implicit bias “likely plays a role in this observation.”⁵⁸ Similarly, the National Heart, Lung, and Blood Institute Working Group at the National Institutes of Health found that “undiagnosed VHD appears to be more common in lower socioeconomic groups...Patients who are women, Black, or on Medicaid are less likely to be screened for progression of VHD at appropriate intervals.”⁵⁹ Patients who have private insurance have also been found to be “more likely to undergo minimally invasive surgery than patients with Medicaid or without insurance,” further exacerbating racial and ethnic treatment disparities.⁶⁰ As a result, although these patients if diagnosed with AS would be eligible for TAVR, nonetheless too frequently do not receive it. This is a system failure that results in too many minority and underserved patients being denied the standard of care.

Edelman and Thourani assert in their 2021 Editorial in the *Journal of the American Heart Association* that “Racial inequality in the diagnosis, treatment, and outcomes of cardiovascular disease has been well documented...Potential targets to correct inequality require increased understanding of the true prevalence of AS among different races, improved access to health care, and an improvement in the relationship and trust between the healthcare system and people from diverse racial and ethnic groups.”⁶¹

Lack of Diversity in Cardiovascular Clinical Trials and VHD Clinical Research

Lack of diversity in cardiovascular clinical trials and in the clinical research enterprise compounds existing health disparities and diminishes the impact of promising treatments. Historically, clinical trials across disease states have suffered from under-enrollment of racial and ethnic minorities, compromising the generalizability of clinical research findings to all patient populations.⁶² A study

⁵⁶ Edelman JJ, Thourani VH. Racial Disparity in the Treatment of Aortic Stenosis. *J Am Heart Assoc.* 2021;10(14):e019875. doi:10.1161/JAHA.120.019875

⁵⁷ Lamprea-Montealegre et al. Valvular Heart Disease in Relation to Race and Ethnicity: JACC Focus Seminar 4/9.

⁵⁸ Ibid.

⁵⁹ Lindman BR, Arnold SV, Bagur R, et al. Priorities for Patient-Centered Research in Valvular Heart Disease: A Report From the National Heart, Lung, and Blood Institute Working Group. *J Am Heart Assoc.* 2020;9(9):e015975. doi:10.1161/JAHA.119.015975

⁶⁰ Laurent Glance et al. Racial and Ethnic Disparities in Access to Minimally Invasive Mitral Valve Surgery.

⁶¹ Edelman JJ, Thourani VH. Racial Disparity in the Treatment of Aortic Stenosis.

⁶² National Academies of Sciences, Engineering, and Medicine; Policy and Global Affairs; Committee on Women in Science, Engineering, and Medicine; Committee on Improving the Representation of Women and Underrepresented Minorities in Clinical Trials and Research, Bibbins-Domingo K, Helman A, eds.



of clinical trials between 2006 and 2020 for FDA-approved cardiovascular medications found that less than 3% of clinical trial participants were Black.⁶³ Because treatment efficacy and safety may differ across different populations, it is imperative that clinical trials match the changing demographics of the U.S. patient population. Despite public-private strategies to boost clinical trial diversity, racial and ethnic minorities continue to be underrepresented in these critical studies.

“VHD research should incorporate implementation of science methods to systematically identify and overcome barriers to access to medical treatment and surgical and trans-catheter therapies among race and ethnic minorities. The current unacceptably low rate of these interventions among racial and ethnic minorities should be a call to action and put health care disparities at the forefront of the VHD research and care.”

- Roundtable Participant

In addition to clinical trials, minority underrepresentation across the entire spectrum of clinical research on VHD also severely limits understanding the disease and designing effective – and inclusive – early detection and treatment strategies. As discussed, there are significant racial disparities in TAVR utilization. Despite these longstanding inequities, Black and other minority patients have been underrepresented in studies for new technology used in the treatment of AS, therefore weakening the validity of treatment recommendations and stifling innovation.⁶⁴ VHD researchers should proactively address racial and ethnic disparities, as well as other factors that have deterred minority patient participation in clinical research, early in study design.⁶⁵ Diverse data is also critical to helping inform VHD registries, which are invaluable to advancing medical knowledge and improving patient outcomes.⁶⁶

WHERE WE NEED TO GO: 2023 ROUNDTABLE RECOMMENDATIONS

Over the course of the convening, participants were encouraged to recommend concrete actions that can be taken to address gaps in care for minority patients with VHD. Recommendations were made during the various discussion sessions as well as through a discussion worksheet on which

Improving Representation in Clinical Trials and Research: Building Research Equity for Women and Underrepresented Groups. Washington (DC): National Academies Press (US); May 17, 2022.

⁶³ Chen S, Li J. Participation of Black US Residents in Clinical Trials of 24 Cardiovascular Drugs Granted FDA Approval, 2006-2020. *JAMA Netw Open*. 2021 Mar 1;4(3):e212640. doi: 10.1001/jamanetworkopen.2021.2640. PMID: 33755163; PMCID: PMC7988366.

⁶⁴ Edelman JJ, Thourani VH. Racial Disparity in the Treatment of Aortic Stenosis.

⁶⁵ Lamprea-Montealegre et al. Valvular Heart Disease in Relation to Race and Ethnicity: JACC Focus Seminar 4/9.

⁶⁶ Ibid.



participants enumerated any additional recommendations or priorities they wished to raise up to ABC. Moreover, the final roundtable session was dedicated to a discussion about recommendations and next steps. The recommendations illustrate the importance of a collaborative, multi-stakeholder approach in addressing inequities and improving diagnosis and treatment of VHD in minority patients. Due to the extensive number of recommendations, the ABC distributed a follow-up survey among meeting participants in order to further prioritize top items for action. Please note that the following recommendations are a summary from event discussions and discussion worksheets and do not imply endorsement from any of the event attendees other than the ABC.

“We need action, we need government, we need policymakers to make changes, we need Congress, we need industry, and we need to just strengthen that path for our patients to get care, and we need to convince the patients to also come out and get care.”

- ***Roundtable Participant***

Priority Recommendations for Action in the Near-Term

Roundtable members urge the ABC to:

- Send a letter to the Centers for Medicare and Medicaid Services (CMS) formally requesting reconsideration of the current Coverage with Evidence Development (CED) requirements for Trans Aortic Valve Replacement (TAVR), and within that correspondence, request a follow-up meeting with the agency to further discuss how the CED currently thwarts minority patient access to TAVR and should be retired.
- Meet with the Food and Drug Administration (FDA) to discuss how the agency should hold industry accountable for representativeness in clinical trials and how ensuring diversity in trials will advance equity in cardiology; as part of this effort, meet with the FDA Office of Minority Health and Health Equity.
- Continue to engage in education and outreach efforts with clinical, industry, and patient advocacy partners to boost awareness of VHD and appropriate treatments.

*Roundtable members urge the **federal government** to:*

- Improve access to care (not just insurance coverage but actual access to providers) so patients can get the diagnoses and treatment they need without barriers.
- Support local and national outreach and awareness efforts, including a range of providers (e.g., nurses, physicians, pharmacists, health educators, community health workers) to boost patient awareness of signs, symptoms, and treatment for VHD.



Complete Set of Roundtable Recommendations

ASSOCIATION OF BLACK CARDIOLOGISTS

- Meet with the National Heart, Lung, and Blood Institute (NHLBI), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institute on Minority Health and Health Disparities (NMHD), and the National Institutes of Health (NIH) Director to discuss health inequities and disparities in VHD.
- Send a letter to CMS formally requesting reconsideration of CED requirements for TAVR, and within that correspondence, request a follow-up meeting with the agency to further discuss how the CED currently thwarts minority patient access to TAVR and should be retired.
- Meet with FDA to discuss how the agency should hold industry accountable for representativeness in clinical trials and how ensuring diversity in trials will advance equity in cardiology; as part of this effort, meeting with the FDA Office of Minority Health and Health Equity.
- Meet with the U.S. Health and Human Services' Office of Minority Health to discuss an all-of-HHS approach to VHD in minority patients.
- Meet with the Agency for Healthcare Research and Quality (AHRQ) to discuss areas of research the agency should pursue to help advance equity and address disparities in VHD.
- Urge Congress to add an enforcement mechanism to current FDA requirements mandating that clinical trial sponsors submit diversity action plans to the FDA.
- Continue to engage in education and outreach efforts with clinical, industry, and patient advocacy partners to boost awareness of VHD and appropriate treatments.
- Engage directly with primary care providers, primary care associations, and other groups (e.g., community health centers) to educate them about the equity issues associated with VHD among minority patients to increase screening, diagnosis, and treatment.
- Work with other cardiology societies to develop an accessible educational tool for non-cardiologists to help them think more regularly about VHD, particularly among their female and minority patients, and elevate it higher in their process of differential diagnosis (e.g., "Could it be VHD?")

FEDERAL GOVERNMENT

GENERAL RECOMMENDATIONS

- Continue to leverage a whole-of-government approach to addressing social determinants of health (SDOH) to help dismantle long-standing health inequities and improve quality of care and health outcomes for minority patients; such efforts should include advancing training regarding implicit bias and how it impacts quality of care and outcomes for minority patients.



- Support local and national outreach and awareness efforts, including a range of providers (e.g., nurses, physicians, pharmacists, health educators, community health workers) to boost patient awareness of signs, symptoms, and treatment options for VHD.
- Improve access to care (not just insurance coverage but actual access to providers) so patients can get appropriate and timely diagnoses and treatment.
- Acknowledge that systemic racism contributes directly to SDOH, which in turn undermines health and well-being among individuals and communities of color.
- Create a pilot VHD screening program involving primary care providers, family physicians, and advanced practice nurses to ensure that people with risk factors for VHD are screened and anyone with VHD learns of their condition and can seek care/treatment.
- Break down data silos across agencies to improve shared decision-making and overall patient care.
- Establish a pilot patient navigator program that specifically supports minority and underserved VHD patients from diagnosis through treatment so more of these patients receive standard of care for VHD.

CMS

- Before the end of 2023, retire the Coverage with Evidence Development (CED) on TAVR and issue an affirmative National Coverage Determination (NCD) according to its FDA-approved indications, as existing data demonstrates that there is no longer a relationship between volume and health outcomes.
- Implement high-impact quality measures that help further identify gaps in VHD for minority patients and better understand overall incidence and prevalence rates in minority communities.
- Test and support models that encourage the integration and coordination of primary and specialty care to assist in VHD detection, promote the adoption of innovative technologies, and stimulate participation of providers that care for underserved patient populations.
- Create payment policies and programs that will advance efforts to diagnose VHD via echocardiogram/Artificial Intelligence (AI) and improve referral to cardiac follow-up care for all individuals diagnosed with VHD.
- Provide payment incentives to make diagnostic tools more widely available in minority communities.
- Increase payments to providers who treat traditionally underserved patients and communities, recognizing additional resources are necessary to address health disparities and access issues.
- Hold providers accountable for ensuring that minority and female patients receive the appropriate standard of care in VHD.
- Cover and reimburse echocardiograms for screening for VHD without a requirement of prior authorization or demonstration of “medical necessity.”



CONGRESS

- Mandate changes for clinical trial data collection methodology to promote data quality and trial integrity; as part of this effort, add an enforcement mechanism (e.g., financial penalties) to current FDA requirements mandating that clinical trial sponsors submit diversity action plans to the FDA.
- Enact legislation that provides incentives to industry to develop medical products for VHD and rewards nationally representative demographic trials (e.g., 1983 Orphan Drug Act).
- Consider Medicare and Medicaid expansion reforms such as lowering the age of eligibility, creating a Medicare buy-in program, and offering robust financial incentives to non-Medicaid expansion states to help reduce coverage gaps.
- Provide competitive grants to improve and expand a diverse cardiovascular clinical workforce.
- If CMS does not take action to retire the CED policy for TAVR, enact a statute that prohibits the agency from continuing the policy and requires the agency to provide coverage and reimbursement for TAVR without restrictions.
- Increase the supply of cardiology providers by increasing opportunities throughout the education pipeline, especially by funding an increasing number of residency slots.

FDA

- Hold industry sponsors accountable in a meaningful way to have clinical trial populations that reflect/match the population intended to use the treatment/intervention.
- Hold the Center for Devices and Radiological Health (CDRH) accountable for achieving the “*Advance Health Equity*” strategic priority outlined in its 2022-2025 plan,⁶⁷ which states, among proposed strategies and actions, that CDRH will “partner with patients, health care providers, industry, and payers to advance solutions that promote equity along the total product life cycle, including access to care.”

NIH & RESEARCH COMMUNITY

- The NHLBI should revisit and provide an annual update on its “2019 Priorities for Patient-Centered Research in Valvular Heart Disease: A Report from the National Heart, Lung, and Blood Institute Working Group” published in the April 2020 *Journal of the American Heart Association* and update stakeholders on the status regarding recommendations.
- Review specialty society and USPSTF guidelines on echocardiogram screening/detection for high-risk and underserved communities.
- Sponsor demonstration projects that support clinical trial enrollment diversity and VHD diagnosis in minority communities.

⁶⁷ Food and Drug Administration. Center for Devices and Radiological Health. 2022-2025 Strategic Priorities. <https://www.fda.gov/media/155888/download>



- Ensure that patients are at the table and engaged throughout the research process, including the end-points of interest to all parties involved.
- Consider ways that real-world evidence can be collected to support and advance understanding and treatment of VHD.
- Enhance the VHD data infrastructure, including the collection of SDOH data, to bolster evidence-based policies and practices aimed at reducing health disparities.
- Support training programs such as fellowships for clinicians of color so there is a more diverse network of providers available to perform VHD procedures across the country.

HEALTH PLAN PAYORS (GOVERNMENT AND COMMERCIAL)

- Limit restrictive prior authorization practices of cardiac tests and treatments that delay timely access to care.
- Prioritize “value over volume” by adjusting payment models to support whole-person care to allow greater alignment of incentives regarding diagnosis and treatment
- Expand coverage of VHD providers and hospitals to reduce inequities in surgical care.
- Remove payment barriers that hurt providers located in underserved and hard-to-reach communities.
- Establish a specific quality measure tied to ensuring that underrepresented patients are screened and appropriately treated for VHD (e.g., TAVR).
- Ensure that TAVR is covered and paid for all patients for whom it is clinically indicated.

INDUSTRY

- Convene C-suite executives to address health equity and existing challenges, such as TAVR underutilization among minority patients and low minority representation in clinical trials.
- Make the business case for diversity, equity, and inclusion; as part of this effort, illustrate the positive economics of ensuring that all patients – particularly minority patients – who have VHD are diagnosed and treated in a timely and state-of-the-art manner.
- Support innovation of screening technologies and other diagnostic tools that assist with prevention and diagnosis of vascular heart disease.
- Develop and disseminate direct-to-patient marketing campaigns featuring targeted interventions that encourage VHD prevention and diagnosis.
- Explore medical product design strategies that deliver products at the lowest cost to the patient without compromising quality standards.
- Innovate programs that promote clinical efficiencies, enhance diagnostic accuracy upstream, reduce workflow delays, and allow for more individuals that meet indications for therapy to access therapy in a timely fashion.
- Provide funding/sponsor fellows to expand the network of interventional cardiologists to ensure that all hospitals can provide access to valvular heart disease treatment strategies.



- Hold academic institutions accountable for representative enrollment in clinical trials by including diversity among the factors that companies use to assess a clinical site for a study.
- Help fund grassroots efforts that aim to address racial health disparities; as part of this effort, target resources to organizations that emphasize elevating Black community members who are addressing racial disparities.
- Leverage technology as an enabler of clinical trial diversity strategies in biopharma and medical device innovation.
- Engage in collaborations with other companies to address diversity in clinical trials and share lessons learned.
- Reframe issues of diversity, equity, and inclusion as “emerging markets” to illustrate the economic (not just moral) value of addressing SDOH.

PATIENT ADVOCACY ORGANIZATIONS

- Actively help to involve constituents in clinical research so they can contribute to trial design and diversify participation/enrollment.
- Highlight and spotlight patients’ stories for awareness and advocacy efforts, specifically using examples that underscore gender/sex disparities in VHD.
- Hold government agencies, payors, industry, and medical professional societies accountable to the VHD health equity objectives to which they have made a commitment by asking for regular report-outs on actions taken and the impact made.
- Empower patients with health information and resources to strengthen informed decision-making related to VHD, including helping them learn about the signs and symptoms of VHD and the range of treatments available, so they can engage in self-advocacy.
- Provide educational resources and other forms of assistance to help patients seek and receive VHD care from high-quality proceduralists and surgeons in addition to treatment centers.
- Partner with heads of industry to produce and distribute VHD patient education resources.
- Help fill data gaps that specifically address prevalence, cost barriers, and economic value of TAVR.
- Increase education on gender disparities that exist within VHD and help dismantle stigmas/stereotypes that portray heart disease as a “man’s disease.”
- Further leverage annual Heart Valve Disease Awareness Day to reach more individuals, families, and clinicians to improve diagnosis and treatment, with a particular focus on diverse individuals and communities.
- Engage in efforts to ensure diversity and inclusion among volunteer advocates and staff so that patient organizations are more representative of the communities they seek to serve.



- Help ensure prospective patients can speak to a TAVR patient who has had a similar lived experience; as part of this effort, continue to work to diversify the participants in patient-to-patient initiatives such as, but not limited to, the TAVR Visiting Program.

PROVIDERS AND MEDICAL PROFESSIONAL SOCIETIES

- Utilize state-of-the-art screening tools and better technologies to reduce misdiagnosis and underdiagnosis of VHD.
- Help increase awareness of VHD among non-cardiologists and the vital importance of cardiovascular screenings across the lifespan.
- Support the development and facilitation of community-based VHD screening programs to meet patients where they are and support efforts to ensure follow-up for treatment.
- Design a more streamlined, patient-friendly approach to imaging so minority patients, in particular, can minimize the amount of time they need to take away from work, school, family, etc.; as part of this effort, be mindful of the disproportionate negative impact of lost time/wages disproportionately on patients of color and challenging socio-economic status when they have to seek testing.
- Train providers to adopt “upstream” approaches to emphasize risk factor modification and address impacts of SDOH on whole-person care; ensure medical education and residency and fellowship programs include teaching about health equity.
- Recruit and retain a diverse and inclusive cardiovascular clinical workforce through workforce development programs, mentorship opportunities, and continuing education in the field of cardiology.
- Strengthen the next generation of clinicians by incorporating DEI-focused training programs into medical education, including implicit bias training.
- Employ a multi-disciplinary care approach that connects patients to patient navigators, social workers, community resources, pharmacists, and other resources.
- Engage with patients and their family members where they “live, play, and pray” to help build trusted provider-patient relationships.
- Emphasize and help address the impact of systemic racism on patient care experiences and outcomes.
- Provide patient-friendly educational resources to promote health literacy within VHD, in particular.
- Ensure that medical journals/publications require that study populations are diverse as part of their publication criteria.
- Engage more primary care providers and other non-cardiologists in recognizing the importance of diagnosing and treating VHD; as part of this effort, ensure clinicians understand the risk factors and common accompanying conditions (e.g., diabetes) with VHD.
- Build a trusted referral network of high-volume hospitals to help reduce access inequities around VHD surgical care.



Peer-Reviewed Research on Underrepresented Minority (URM) Patients with Aortic Stenosis

The Association of Black Cardiologists (ABC) has been integral to advancing research around the underutilization of TAVR among people of color.

The following studies are presented in chronological order, with the most recent at the top.

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**An ABC Roundtable:
Continuing to Address Gaps in Care in
Minority Patients with Valvular Heart Disease**

February 24, 2023

11:00 AM – 4:15 PM EST

Venable LLP

600 Massachusetts Avenue NW

Washington, DC 20001

MEETING AGENDA

- | | |
|----------------------------|---|
| 11:00 AM – 11:15 PM | Registration and Lunch |
| 11:15 – 11:25 AM | Welcome and Housekeeping <ul style="list-style-type: none">▪ Moderator: Ilisa Halpern Paul Senior Policy Advisor, Venable LLP▪ Dr. Anekwe Onwuanyi President, Association of Black Cardiologists (ABC) |
| 11:25 – 11:45 AM | Agenda, Meeting Objectives and Participant Introductions <ul style="list-style-type: none">▪ Moderator: Ilisa Halpern Paul Senior Policy Advisor, Venable LLP▪ Dr. Seun Alli Co-Chair, Structural Heart Disease Task Force Program Association of Black Cardiologists (ABC)▪ Dr. Aaron Horne Co-Chair, Structural Heart Disease Task Force Program Association of Black Cardiologists (ABC) |
| 12:05 – 12:50 PM | Session I: Understanding the Challenges: Where We Were, Where We Are and Where We Need To Go <ul style="list-style-type: none">▪ Moderator: Ilisa Halpern Paul Senior Policy Advisor, Venable LLP▪ Dr. Seun Alli Co-Chair, Structural Heart Disease Task Force Program Association of Black Cardiologists (ABC)▪ Dr. Aaron Horne Co-Chair, Structural Heart Disease Task Force Program Association of Black Cardiologists (ABC) |



12:05 – 12:50 PM

Session II: Understanding Clinical and Industry Perspectives

- **Moderator: Ilisa Halpern Paul**
Senior Policy Advisor, Venable LLP
- **Dr. Yele Aluko**
Chief Medical Officer, EY Americas
Director, EY Center for Health Equity
Former Interventional and Structural Heart Cardiologist
Novant Health Inc.
- **Dr. Antoine Keller**
Member, Diversity and Inclusion Committee
American College of Cardiology (ACC)
Cardiovascular Thoracic and Endovascular Surgeon
Ochsner Lafayette General Hospital

12:50 – 1:00 PM

Break

1:00 – 1:45 PM

Session III: Government Perspectives

- **Moderator: Ilisa Halpern Paul**
Senior Policy Advisor, Venable LLP
- **Dr. Patrice Desvigne-Nickens**
Medical Officer
Heart Failure and Arrhythmias Branch Division
of Cardiovascular Diseases
National Heart, Lung, and Blood Institute (NHLBI)
National Institutes of Health (NIH)
- **Dr. Dora Hughes**
Chief Medical Officer
CMS Innovation Center (CMMI)
Centers for Medicare & Medicaid Services (CMS)
- **Amber Ray**
Health Policy Advisor and Deputy Legislative Director
Office of Lisa Blunt Rochester (D-DE)
U.S. House of Representatives
- **Dr. Bernard Vasseur**
Medical Officer, Office of Cardiovascular Devices
Division of Circulatory Support, Structural
and Vascular Devices
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)



1:45 – 2:45 PM

**Session IV: Public Policy and Patient Advocacy,
Awareness and Engagement Efforts**

- **Moderator: Ilisa Halpern Paul**
Senior Policy Advisor, Venable LLP
- **Celina Gorre**
CEO, WomenHeart
- **Dr. Arik King**
Patient
- **Sue Peschin**
President and CEO
Alliance for Aging Research
- **Dr. Gary Puckrein**
President and CEO
National Minority Quality Forum (NMQF)

2:45 – 3:00 PM

Break

3:00 – 4:05 PM

**Session V: Consensus Building for Recommendations
and Action Steps**

- **Moderator: Ilisa Halpern Paul**
Senior Policy Advisor, Venable LLP

4:05 – 4:15 PM

Next Steps and Final Reflections

- **Moderator: Ilisa Halpern Paul**
Senior Policy Advisor, Venable LLP
- **Dr. Seun Alli**
Co-Chair, Structural Heart Disease Task Force Program
Association of Black Cardiologists (ABC)
- **Dr. Aaron Horne**
Co-Chair, Structural Heart Disease Task Force Program
Association of Black Cardiologists (ABC)

4:15 PM

Adjourn



Roundtable Attendee List

Thought Leaders

Yele Aluko, MD, MBA, FACC, FSCAI
Chief Medical Officer, EY Americas, Director, EY Center for Health Equity
Former Interventional and Structural Heart Cardiologist, Novant Health Inc.

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Senior Vice President of Health Education and Advocacy, Alliance for Aging Research

Rimsky Denis, MD, MPH, MBA
Cardiology Fellow, Structural Cardiology, The Johns Hopkins Hospital

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National Heart, Lung, and Blood Institute (NHLBI), National Institutes of Health (NIH)

Dechane Dorsey, JD
Executive Director, AdvaMed Accel, AdvaMed

Tekisha Dwan Everette, PhD, MPA, CPH
Executive Vice President, Trust for America's Health (TFAH)

Charles Gill
Senior Director, Marketing, MedStar Health

Celina Gorre, MPA, MPH
Chief Executive Officer, WomenHeart

Phyllis Greenberger, MSW
Senior Vice President, HealthyWomen

Derek M. Griffith, PhD
Board Member, Men's Health Network (MHN)
Co-Director Racial Justice Institute, Director Center for Men's Health Equity, and
Professor of Health Management and Policy, Georgetown University

Dora Hughes, MD, MPH
Chief Medical Officer, CMS Innovation Center (CMMI), Centers for Medicare & Medicaid Services (CMS)



Mark Jenkins, MD, FACC
Former Board Member, Association of Black Cardiologists (ABC),
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Heart Failure Cardiologist, ChristianaCare Hospital

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Member, 100 Black Men of America
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Arik King, EdD
Patient

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Account Executive, CURA Strategies

Angelo Moore, PhD, MSN, RN, NE-BC
Chair, Scholarship & Awards Committee, National Black Nurses Association (NBNA)
Assistant Director, Community Outreach, Engagement, and Equity (COEE), Duke Cancer Institute

Sue Peschin, MHS
President and Chief Executive Officer, Alliance for Aging Research

Gary Puckrein, PhD
President and CEO, National Minority Quality Forum (NMQF)

Amber Ray, PharmD, MPH
Health Policy Advisor and Deputy Legislative Director
Office of Lisa Blunt Rochester (D-DE), U.S. House of Representatives

Margot Savoy, MD, MPH, FAFAP
Senior Vice President, Education, Inclusiveness and Physician Well-Being
American Academy of Family Physicians (AAFP)

Triston Smith, MD, FSCAI, SQIL
Member, Diversity, Equity, and Inclusion (DEI) Taskforce
Society for Cardiovascular Angiography and Interventions (SCAI)
Co-Chair Structural Heart Clinical Council, CommonSpirit Health
Medical Director, Cardiovascular Service Line and Structural Heart Interventions, Trinity Health System,
Medical Director of Cardiology, East Ohio Regional Hospital



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Member, Society of Thoracic Surgeons (STS)
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Surgical Director, Aortic Institute, Yale New Haven Health Heart & Vascular Center,
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Association of Black Cardiologists

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Yardly Pollas-Kimble, JD
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Sponsors and Observers

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