

JACC COUNCIL PERSPECTIVES

Aortic Valve Stenosis Treatment Disparities in the Underserved



JACC Council Perspectives

Wayne Batchelor, MD, MHS,^{a,b} Saif Anwaruddin, MD,^{a,c} Laura Ross, PA-C,^{a,d} Oluseun Alli, MD, MHA,^e Michael N. Young, MD,^{a,f} Aaron Horne, MD, MBA, MHS,^g Abby Cestoni, BBA,^a Frederick Welt, MD,^{a,h} Roxana Mehran, MD^{a,i}

ABSTRACT

Underserved minorities make up a disproportionately small subset of patients in the United States undergoing transcatheter and surgical aortic valve replacement for aortic stenosis. The reasons for these treatment gaps include differences in disease prevalence and patient, health care system, and disease-related factors. This has major implications not only for minority patients, but also for other groups who face similar challenges in accessing state-of-the-art care for structural heart disease. The authors propose the following key strategies to address these treatment disparities: 1) implementation of measure-based quality improvement programs; 2) effective culturally competent communication and team-based care; 3) improving patient health care access, education, and effective diagnosis; and 4) changing the research paradigm that creates an innovation pipeline for patients. Only a concerted effort from all stakeholders will achieve equitable and broad application of this and other novel structural heart disease treatment modalities in the future. (J Am Coll Cardiol 2019;74:2313–21) © 2019 by the American College of Cardiology Foundation.

In 1968, Drs. Ross and Braunwald published a steep drop-off in survival following the development of severe symptomatic aortic valve stenosis (AS) (1). With the advent of surgical aortic valve replacement (SAVR) and transcatheter aortic valve replacement (TAVR), highly effective treatments now exist for AS, dramatically improving prognosis. Unfortunately, these innovations have not been

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From the ^aAmerican College of Cardiology Interventional Cardiology Sectional Leadership Committee, Washington, DC; ^bInova Center of Outcomes Research, Inova Heart and Vascular Institute, Falls Church, Virginia; ^cDivision of Cardiovascular Medicine, Perelman School of Medicine at the University of Pennsylvania Hospital, Philadelphia, Pennsylvania; ^dPark Nicollet Heart and Vascular Center, St. Louis Park, Minnesota; ^eNovant Heart and Vascular Institute, Charlotte, North Carolina; ^fCardiology Division, Dartmouth-Hitchcock Medical Center, Geisel School of Medicine at Dartmouth, Dartmouth, New Hampshire; ^gHeart and Vascular Specialists of North Hills, HCA Healthcare, North Richland Hills, Texas; ^hUniversity of Utah Health, Salt Lake City, Utah; and ⁱThe Zena and Michael A. Wiener Cardiovascular Institute, Icahn School of Medicine at Mount Sinai, New York, New York. Dr. Batchelor has received institutional grant/research support from and served as a speaker for Boston Scientific; has served as a consultant for Abbott; and has served on the Speakers Bureau of Boston Scientific, Abbott, and Medtronic. Dr. Anwaruddin has served as a proctor and speaker for Medtronic and Edwards Lifesciences; and has served on the Advisory Board of Medtronic. Dr. Alli has served as a consultant for Edwards Lifesciences, Abbott, and Boston Scientific. Dr. Horne has received honoraria for KOL activities with Edwards Lifesciences, CSL, and Zoll. Dr. Welt has served on the Advisory Board of Medtronic. Dr. Mehran has received institutional grant/research support from Daiichi-Sankyo/Eli Lilly, Bristol-Myers Squibb, AstraZeneca, The Medicines Company, OrbusNeich, Bayer, CSL Behring, Abbott Laboratories, Watermark Research Partners, Novartis Pharmaceuticals, Medtronic, AUM Cardiovascular, and Beth Israel Deaconess Medical Center; has served as a consultant for and/or executive committee of Janssen Pharmaceuticals, Osprey Medical, Watermark Research Partners, Medscape, The Medicines Company, Boston Scientific, Merck, Cardiovascular Systems, Sanofi, Shanghai BraccoSine Pharmaceutical, and AstraZeneca; and has equity in Claret Medical and Elixir Medical Corporation. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose. Hassan Baydoun, MD, served as Guest Associate Editor for this paper.

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**ABBREVIATIONS
AND ACRONYMS****AA** = African American**AS** = aortic stenosis**SAVR** = surgical aortic valve replacement**TAVR** = transcatheter aortic valve replacement**VHD** = valvular heart disease

equally disseminated across the spectrum of patients afflicted with AS; multiple studies have shown treatment disparities that particularly affect underserved minorities. The extent to which these disparities are related to disease prevalence, genetics, social demographics, and/or referral and treatment biases remains unclear. To follow is a review of the underdiagnosis and treatment of AS in underserved populations and how this issue might be best addressed.

WHO ARE THE “UNDERSERVED?”

When discussing disparities, emphasis is often placed on racial and ethnic minorities, most notably African Americans (AAs) and Hispanics. Admittedly, these 2 groups will form the basis of much of our review. However, there are other groups who may face similar disparities in care, but in whom our understanding of this phenomenon is poor due to limited data. For example, there exists limited data on the treatment of AS in American Indians, Alaska Natives, Asians, and Pacific Islanders. The geographic regions in which many of these minority groups reside, such as Alaska and Hawaii, have a lower density of TAVR programs (2). Another often overlooked underserved group, rural Americans, also faces challenges in accessing care (3). It has recently been shown that Floridians living in the most rural counties travel an additional 44 miles for TAVR and face a 7-fold lower rate of TAVR utilization compared with densely populated regions (4). Therefore, the “underserved” may include not only minorities, but also patients who may have restricted aortic valve replacement (AVR) access due to other factors, including living conditions and/or geography.

DOES RACE/ETHNICITY INFLUENCE THE PREVALENCE OF AS?

A National Heart, Lung, and Blood Institute population-based study derived from 11,911 adults estimated the prevalence of AS to be 0.4% (5). Prevalence varied from 0.02% in subjects age 18 to 44 years to 2.8% in subjects over age 75 years. Although drawn from a reasonably diverse patient cohort (40% black, 59% white, and 1% other), data for minorities were not reported separately. Most prevalence data have been drawn from in-patient hospital and/or echocardiographic databases. A large series of 40,419 patients undergoing valve surgery at the Cleveland Clinic from 1993 to 2007 showed that, compared with Caucasians, AAs had a lower prevalence of AS, aortic valve calcification, bicuspid aortic valve disease, and

HIGHLIGHTS

- Underserved minorities represent a low proportion of patients undergoing TAVR and SAVR.
- Differences in disease prevalence and patient, disease, and health system-related factors may all contribute to treatment disparities.
- We present a 4-part intervention aimed at narrowing this treatment gap.
- A collaborative effort from all stakeholders is necessary to achieve equity.

mitral valve prolapse (6). Data from the Nationwide Inpatient Sample also reported a lower prevalence of AS in AAs, Hispanics, and Asian/Pacific Islanders (7). AS was positively correlated with income, suggesting that higher socioeconomic status may have caused a detection bias. In contrast, a prospective study of 2,805 elderly patients who underwent echocardiography in a New York long-term care facility revealed no difference in AS prevalence across AAs, Caucasians, and Hispanics (8). The largest prevalence study to date examined 272,429 patients undergoing echocardiography at the Vanderbilt University Medical Center (9). In this series, the prevalence of AS and bicuspid disease was less in AAs compared with Caucasians. The observation that the prevalence of mitral regurgitation was similar between AAs and Caucasians led the authors to conclude that referral bias was unlikely. Still, it is conceivable that the combination of low socioeconomic status and lack of adequate health care insurance renders AS particularly lethal. If true, this might lower the prevalence of AS in underserved minorities estimated from hospital and echocardiographic databases. Therefore, prevalence studies should ideally account for health care access and socioeconomic status.

Despite these biases, the published data more supports than refutes the notion that AAs and other minorities may have a lower prevalence of AS than Caucasians. To what might this be attributed? First, bicuspid aortic valve disease and aortic valve sclerosis and calcification appear to be less prevalent in AAs (6,9-11). Although genetics may play a role, there are no racial differences in the penetrance of the single nucleotide polymorphisms associated with AS (12,13). Differences in the prevalence of AS risk factors also do not account for the prevalence data. Hypertension, diabetes mellitus, and hyperlipidemia have been shown to be independent risk factors for AS (14).

TABLE 1 Inclusion and Outcomes of Minorities in TAVR Studies

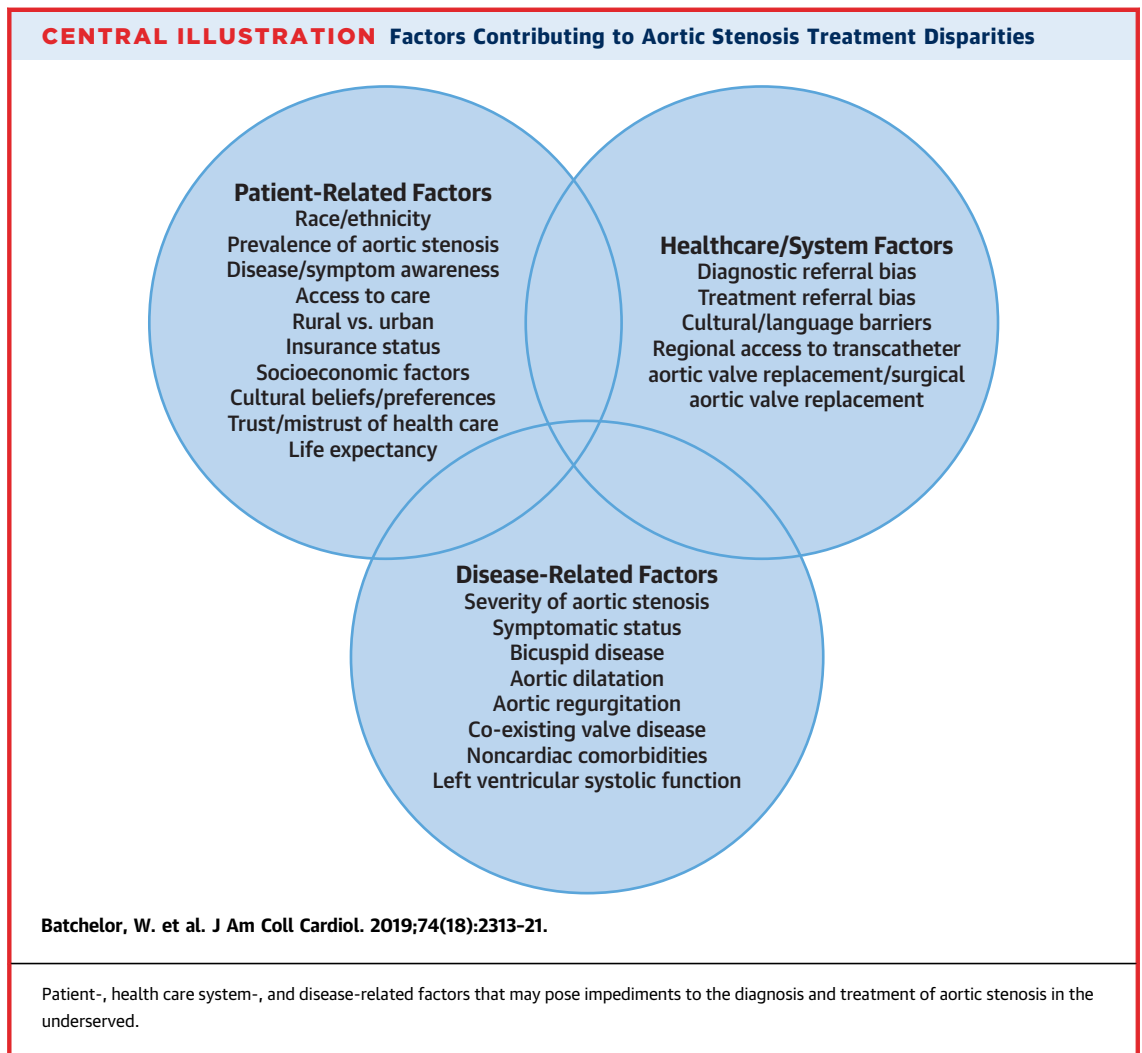
Patient No.	First Author (Ref. #)	Years	Minority	%	Patient Sample	Major Findings
1	Douglas et al. (63)	2007-2009	NW	5.5	Multicenter RCT	• Did not report outcomes by race/ethnicity
2	Minha et al. (42)	2007-2013	AA	11.0	MedStar Washington Hospital database	• TAVR procedures in AAs were less frequently performed as part of a clinical trial, but more frequently for commercial TAVR
3	Thongprayoon et al. (60)	2008-2014	NW	3.0	Mayo Clinic Hospital Minnesota database	• Did not report outcomes by race/ethnicity
4	Yoon et al. (45)	2010-2014	Asian	100.0	Asian TAVR registry	• Comparable TAVR outcomes in Asians, despite anatomical concerns
5	Minutello et al. (61)	2011	NW	18.0	NIS database	• Did not report outcomes by race/ethnicity
6	Hannan et al. (62)	2011-2012	NW	4.6	NYS TAVR database	• Did not report outcomes by race/ethnicity
7	McNeely et al. (44)	2011-2013	AA	3.9	Medicare and Medicaid	• AA and Hispanics showed no differences in 30-day mortality, readmission rates, or discharge home after TAVR
8	Holmes et al. (20)	2011-2013	Hispanic	1.0	STS/ACC TVT	• Did not report outcomes by race/ethnicity
			AA	2.8		
			Asian	0.9		
9	Alqahtani et al. (41)	2011-2014	Other	0.9	NIS database	• Rates of TAVR utilization increased from 0.32%–7.6% in AAs • No difference in utilization rates, in-hospital outcomes, and TAVR cost between Caucasians and AAs
			AA	4.3		
			AA	3.0		
10	Kobrin et al. (64)	2011-2015	AA	3.0	Medicare and Medicaid	• Did not report outcomes by race/ethnicity
11	Carroll et al. (21)	2011-2015	AA	3.7	STS/ACC TVT	• Did not report outcomes by race/ethnicity
			Asian	1.1		
			Other	1.0		
12	Kolte et al. (23)	2011-2016	AA	2.8	STS/ACC TVT	• Did not report outcomes by race/ethnicity
			Hispanic	2.8		
			Other	1.4		
13	Holmes et al. (65)	2012-2014	AA	3.8	STS/ACC TVT	• Did not report outcomes by race/ethnicity
14	Hernandez-Suarez et al. (43)	2012-2014	AA	3.6	NIS database	• Hispanics: increased LOS and in-hospital complications compared with Caucasians
			Hispanic	3.5		
15	Culler et al. (66)	2012-2015	AA	3.9	Medicare	• Did not report outcomes by race/ethnicity
			Hispanic	1.0		
			Other	2.0		
16	Grover et al. (22)	2012-2015	AA	3.8	STS/ACC TVT	• Did not report outcomes by race/ethnicity
			Asian	1.1		
			Hispanic	3.8		
17	Sleder et al. (27)	2013-2014	AA	15.0	Henry Ford Hospital	• AA: less likely to be referred for AVR and more likely to refuse and/or be lost to follow-up
18	Feldman et al. (67) (REPRISE III)	2014-2015	AA	3.0	Multicenter RCT	• Did not report outcomes by race/ethnicity
			Hispanic	2.8		
			Other	0.9		
19	Alkhouli et al. (19)	2011-2016	AA	3.8	STS/ACC TVT	• AA and Hispanics: similar 1-yr TAVR mortality, but more HF hospitalizations • Asian/NA/PI: lower adjusted 1-yr TAVR mortality
			Hispanic	3.4		
			Asian/NA/PI	1.5		

AA = African American; ACC = American College of Cardiology; AKI = acute kidney injury; AMI = acute myocardial infarction; AVR = aortic valve replacement; CVA = cerebrovascular accident; LOS = length of hospital stay; NA = Native American; NB = nonblack; NIS = National Inpatient Sample; NW = nonwhite; NYS = New York State Cardiac Surgery Reporting System; PI = Pacific Islanders; RCT = randomized clinical trial; SAVR = surgical aortic valve replacement; STS = Society of Thoracic Surgeons; TAVR = transcatheter aortic valve replacement; TVT = transcatheter valve therapy.

With AAs and Hispanics bearing a greater burden of these and other atherosclerosis risk factors (15,16), one would expect a *higher* prevalence of AS in these minorities. Therefore, the genetic, clinical, and environmental factors that contribute to a lower reported prevalence of AS in minorities remain largely unknown. Given that the prevalence of AS increases with age, the 3-year longer life expectancy in Caucasians versus AAs might also serve to increase the prevalence in the former versus the latter (17).

DIAGNOSIS, TREATMENT, AND OUTCOMES DISPARITIES

Each year, thousands of minorities develop severe degenerative AS and need AVR. With expanding indications and patient preference, TAVR has become the favored treatment (18). However, the marked growth in TAVR has not been uniform across all demographics. Among the 70,221 patients undergoing TAVR from 2011 to 2016 in the Society of Thoracic



Surgeons/American College of Cardiology (ACC) Transcatheter Valve Therapy Registry, 91% were white, 3.8% black, 3.4% Hispanic, and 1.5% Asian/Native American/Pacific Islander (19). This confirms significant under-representation in minorities relative to their respective proportions of the U.S. population. Several other reports have shown that the proportion of minority TAVR patients is low, usually between 1% and 5% (Table 1) (20-23). Interestingly, similar observations are noted for transcatheter mitral valve repair and left atrial appendage closure (24). To further understand this phenomenon, one must consider the barriers that exist for underserved minorities along the path from diagnosis to treatment. These barriers may be categorized as: 1) patient; 2) health care system; and 3) disease-related (Central Illustration).

PATIENT-RELATED BARRIERS. The diagnosis of AS usually stems from a referral for echocardiography,

often triggered by symptoms or a new systolic murmur. Studies have shown that AAs with AS are less likely to report dyspnea than their Caucasian counterparts (9) and are more likely to attribute chest pain to a gastrointestinal rather than cardiac source (25). The baseline characteristics of AAs with AS also tend to be slightly different, with AAs more likely to present at a younger age, be female, have a higher body mass index, and present with impaired renal function (6). AAs also carry a disproportionate burden of comorbidities, including diabetes mellitus, hypertension, tobacco abuse, obesity, and congestive heart failure (26). These comorbidities may confound or mask the symptoms of AS, potentially delaying diagnosis and treatment.

Patient refusal, insurance status, and social demographics also play a significant role. AAs are more likely to decline AVR and be lost to follow-up (27). Hispanic patients have a nearly 3-fold higher

TABLE 2 Inclusion and Outcomes of Minorities in SAVR Studies

Patient No.	First Author (Ref. #)	Years	Minority	%	Patient Sample	Major Findings
1	Brown et al. (53)	1997-2006	NW	11.0	STS Database	<ul style="list-style-type: none"> Nonwhite patients had a higher mortality from SAVR
2	Taylor et al. (54)	1999-2002	AA	5.1	STS Database	<ul style="list-style-type: none"> AA: similar mortality, stroke and sternal infections post-SAVR AA: higher risk of prolonged ventilation and hospital stay and bleeding
3	Murugiah et al. (55)	1999-2010	AA Other	3.3-3.1 2.9-3.2	Medicare	<ul style="list-style-type: none"> AA: higher rates of 1-yr hospitalization compared with whites AA males: no decline in 1-yr hospitalizations in contrast to all other race and sex subgroups
4	Barreto-Filho et al. (56)	1999-2011	AA NW-NB	3.5-3.2 2.8-3.4	Medicare	<ul style="list-style-type: none"> AA: lower rates of SAVR and higher SAVR mortality AA: longer LOS, hospital costs, and use of intermediate care facilities
5	Yankey et al. (57)	1999-2013	AA	27.0	Duke University Database	<ul style="list-style-type: none"> AA: similar SAVR mortality AA: more comorbidities and less likely to undergo SAVR
6	Zajarias et al. (58)	2000-2011	–	–	STS Database	<ul style="list-style-type: none"> AA: more comorbidities and HF and higher surgical operative mortality AA race was an independent predictor for prolonged ventilation, renal failure, pneumonia, and stroke
7	Chaker et al. (59)	2003-2014	AA Hispanic	5.1 6.0	NIS database	<ul style="list-style-type: none"> Did not report outcomes by race/ethnicity
8	Yeung et al. (34)	2004-2010	AA	10.0	Barnes-Jewish Hospital Database	<ul style="list-style-type: none"> AA: more hypertension, diabetes mellitus, chronic kidney disease, and end-stage renal disease AA: underwent AVR less frequently and refused intervention more often AA: similar 3-yr survival to EA
9	Thongprayoon et al. (60)	2008-2014	NW	7.0	Mayo Clinic Database	<ul style="list-style-type: none"> Did not report outcomes by race/ethnicity
10	Minutello et al. (61)	2011	NW	17.0	NIS Database	<ul style="list-style-type: none"> Did not report outcomes by race/ethnicity
11	Hannan et al. (62)	2011-2012	NW	7.2	NYS AVR Database	<ul style="list-style-type: none"> Did not report outcomes by race/ethnicity
12	McNeely et al. (44)	2011-2013	AA Hispanic	4.8 1.3	Medicare/Medicaid	<ul style="list-style-type: none"> AA: worse unadjusted 30-day and 1-yr mortality than whites or Hispanics. After risk adjustment, no differences in mortality AA: higher adjusted 30-day readmission rates
13	Cruz Rodriguez et al. (26)	2011-2016	AA Hispanic	18.0 11.0	Methodist Health System	<ul style="list-style-type: none"> AA: lower rates of referral to cardiothoracic surgeon

EA = European American; other abbreviations as in Table 1.

uninsured rate than white, non-Hispanic patients. AA and Asian patients also report higher uninsured rates (28). The reluctance of underinsured patients to undergo, and of health care systems to pay for, costly AVRs results in fewer patients receiving treatment (29). Other sociodemographic factors such as income, education level, living conditions, employment status, interpersonal relationships, and exposure to discrimination have also been shown to influence access to health care (30). In patients with limited English proficiency, language barriers may compromise health care access and utilization, particularly in Hispanic and Asian patients (30,31). Exposure to racism and discrimination may also shape a patient's health care attitudes and perceptions. For example, the negative impact of the Tuskegee Syphilis Study still resonates within the older AA community, potentially manifesting as a distrust of the health care system and a reluctance to seek out care and/or participate in research trials (32,33). Therefore, patient-specific factors related to presentation, comorbidities, insurance,

perception/attitudes, and social determinants of health may all result in lower AVR rates in underserved minorities.

BARRIERS WITHIN THE HEALTH CARE SYSTEM.

Once diagnosed, underserved minorities face referral and treatment biases, rendering them less likely to receive care (26,27,34). AAs and Hispanics are less likely to be referred to cardiologists and cardiac surgeons (9,27). Subconscious physician bias and a lack of culturally appropriate communication have been postulated as contributing factors (26,27,34-36). Cardiologists' own awareness of treatment disparities within their practices remains poor, posing another barrier to care (37). Physician-patient interactions that lack cultural awareness and sensitivity prevent patients from gaining the trust necessary for complex shared medical decision-making. The practitioner-patient relationship is strengthened when patients view themselves as similar to their practitioner in terms of personal beliefs, values, and communication (38). Although race concordance is the primary

determinant of this, several other factors are key, including a physician's use of culturally sensitive and patient-centered communication (38). With nonwhite physicians caring for most underserved minorities in the United States, it has been proposed that increasing physician diversity is an integral part of extending our reach to these patients (39).

DISEASE-RELATED FACTORS AND CLINICAL OUTCOMES.

There are several AS disease-related factors that govern treatment decisions (40). The severity of AS, symptomatic status, presence of bicuspid disease, degree of aortic dilation, coexisting valvular heart disease (VHD), concomitant coronary disease, noncardiac comorbidities, and left ventricular systolic function are several factors that may influence the decision to proceed with AVR (40). Whether minorities are prone to have disease-related factors that bias against AVR is unknown. However, it is likely that patient and health care system factors exert more influence on final treatment decisions.

Once selected for AVR, underserved minorities tend to experience favorable outcomes. **Tables 1 and 2** summarize TAVR and SAVR studies reporting outcomes in minorities. Most, but not all, show no differences in mortality among various racial/ethnic subgroups (41,42). Hernandez-Suarez *et al.* (43) recently reported higher rates of post-TAVR complications in Hispanic patients, but no difference in mortality. A propensity analysis of 17,973 TAVR and 95,078 SAVR Medicare patients showed that AAs fared worse following SAVR than Caucasians and Hispanics, but had similar outcomes and readmission rates post-TAVR (44). In a recent report from 29,351 Medicare/Medicaid TAVR patients, the 1-year adjusted mortality was similar in AAs and Hispanics compared with Caucasians and lower in Asian/Native American/Pacific Islanders (19). AA and Hispanic patients had more subsequent heart failure hospitalizations. Most other studies, including the Asian TAVR registry (45), have reported favorable outcomes (**Tables 1 and 2**). Therefore, although underserved minorities are less likely to undergo TAVR, their procedural outcomes tend to be favorable.

CLOSING THE TREATMENT GAP: THE WAY FORWARD

The first step to eliminating treatment disparities is awareness. All stakeholders, including patients, practitioners, health care systems, academic thought leaders, device industry partners, clinical research organizations, regulatory agencies, research funding organizations, payors, and patient advocacy groups must be keenly aware of the existing barriers to care

(**Central Illustration**). The most effective interventions should then be adopted. The ACC's Coalition to Reduce Racial and Ethnic Disparities in Cardiovascular Disease Outcomes (CREDO) has identified the following as strategies to reduce disparate care: 1) performance measure-based quality improvement; 2) provider cultural competency training; 3) team-based care; and 4) patient education (46). Borrowing from these concepts and others, we put forth the following updated suggestions to narrow the AS treatment gap (**Figure 1**).

1. PERFORMANCE MEASURE-BASED QUALITY IMPROVEMENT.

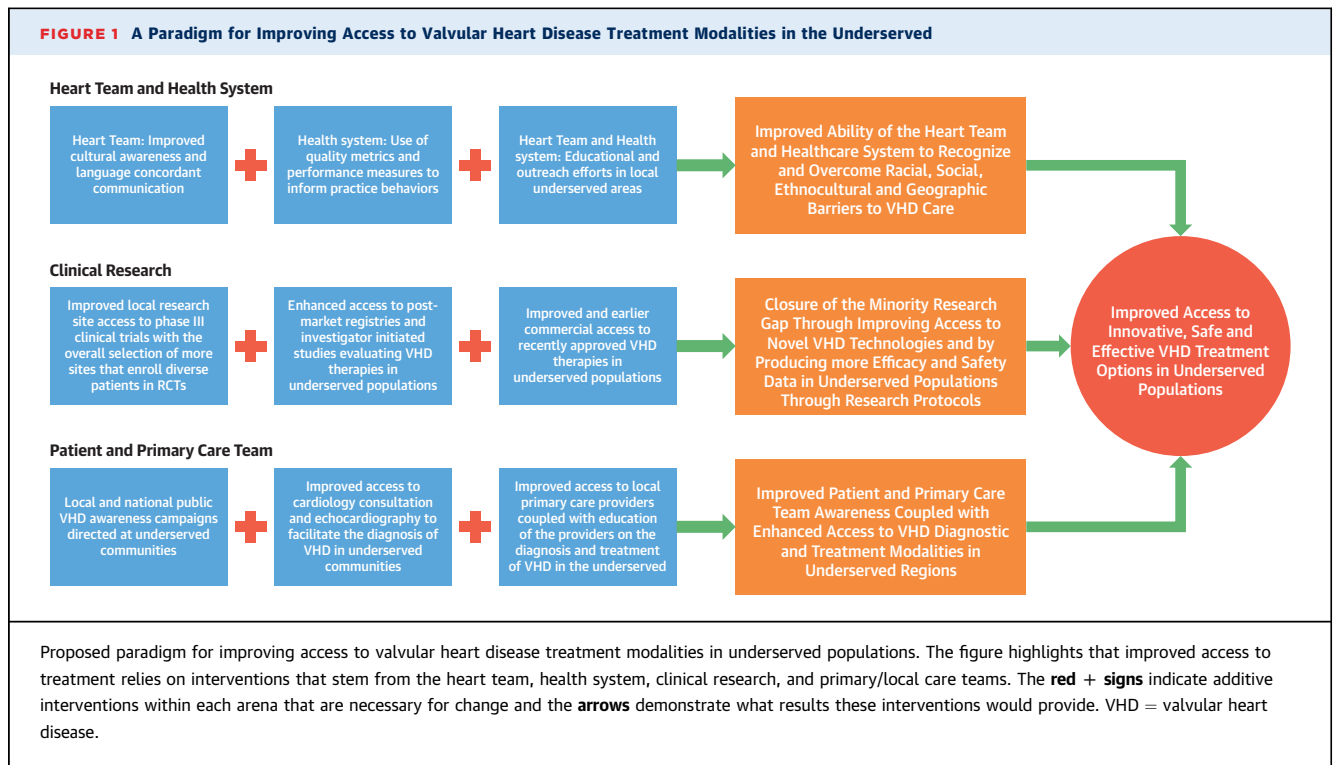
Examining the performance of providers and health care institutions through the use of electronic databases may provide important insights into treatment biases. Several models for this exist and can be emulated (46). An example would be to identify how many underserved minorities with severe symptomatic AS exist within a practice or health system and are being appropriately referred for intervention. This data can then be used to identify impediments to care and known or unknown biases. Performance quality metrics can be used to provide constructive feedback and change behavior. In fact, an entire health care system's ability to provide equitable evidence-based care across all demographic groups can and should be made to be more transparent as with other quality measures.

2. PROMOTING CULTURALLY COMPETENT COMMUNICATION AND TEAM-BASED CARE.

After AS is diagnosed, as "gatekeepers" it is crucial that multidisciplinary heart valve teams play a central role in the consent and decision-making process. Culturally sensitive, clear, and language-concordant communication between the heart team and patients/families helps minimize inappropriate patient refusal. The specific reasons for a patient's refusal of AVR should be sought out and, when appropriate, addressed. Evidence suggests that cultural competency training helps providers be more effective in caring for minority patients (47). Members of the multidisciplinary heart team need to be made aware of, and sensitive to, the inherent biases that might play into decision-making (37).

3. IMPROVING PATIENT HEALTH CARE ACCESS, EDUCATION AND EFFECTIVE DIAGNOSIS.

Improved access to specialized health care, including cardiology and cardiothoracic surgery, is needed in underserved communities. Because elderly patients tend to avoid traveling long distances for their health care and are even willing to accept higher procedural risks to remain local, care should be local whenever possible (48). Based on the recently updated CMS National Coverage Decision (49) and the expert consensus



document put forth by the AATS/ACC/SCAI/STS (50), many community hospitals do not meet the criteria necessary for establishing a TAVR program. Therefore, not infrequently, underserved minorities and patients living in more rural counties are forced to travel for their care.

Educational campaigns are also needed to increase awareness and better inform patients about VHD symptoms, prognosis, and treatment. This may come from health care systems, professional organizations, and/or government or industry-sponsored campaigns. Industry partners may enhance disease or device therapy awareness by supporting culturally sensitive education programs for both patients and referring physicians. Better patient access to high-quality diagnostic echocardiography is another key step. Miniaturized ultrasound and wireless mobile health technologies show promise as cost-effective methods to diagnose VHD at clinics lacking traditional echocardiography (51). These and other novel approaches might expand the reach of echocardiography, which in turn would improve the diagnostic yield of AS within underserved communities.

4. CHANGING THE RESEARCH PARADIGM. The clinical trials that led to U.S. Food and Drug Administration approval of TAVR lacked adequate minority representation. There is an opportunity to close this “minority research gap.” The systematic collection

and reporting of race/ethnicity data in all future structural heart disease research trials is key. The allocation of more trials to clinical investigators who serve underserved minorities also represents an opportunity to ensure that research databases better reflect U.S. demographics. The diversity of research subjects is strongly influenced by the country of enrollment. A recent snapshot of all U.S. Food and Drug Administration drug trials completed in 2015 to 2016 showed that only 1.3% of non-U.S. study participants were AA, whereas this proportion was nearly 15% for those enrolled in the United States (52). Therefore, although enhancing trial enrollment, the globalization of cardiovascular trials may unintentionally result in lower minority enrollment. The expansion of research to sites and investigators who treat and enroll more underserved minorities represents an untapped opportunity. Because these sites also tend to be the first to commercialize newly approved devices, this might also improve underserved minority access to novel therapies in the early phase of commercialization.

CONCLUSIONS

Underserved minorities represent a small subset of patients undergoing AVR. Reports of lower AS prevalence in minorities do not appear to adequately account for this observation. Patient, health care

system, and disease-related factors may all contribute to the treatment gap. There remains a long road ahead to achieving equitable access to TAVR and other innovative treatments for VHD. This has implications not only for underserved minorities, but also for rural Americans who may face similar challenges to accessing care. In the end, only a concerted effort from all stakeholders will allow us to

better “serve the underserved” with these life-saving interventions.

ADDRESS FOR CORRESPONDENCE: Dr. Wayne Batchelor, Inova Heart & Vascular Institute, 3300 Gallows Road, Suite I-4109, Falls Church, Virginia 22042. E-mail: Wayne.Batchelor@inova.org. Twitter: [@_WayneBatchelor](https://twitter.com/_WayneBatchelor).

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