



To Whom It May Concern (CMS Administrator):

The Association of Black Cardiologists offers the following comments on the Centers for Medicare & Medicaid Services' (CMS) National Coverage Analysis (NCA) for Transcatheter Aortic Valve Replacement (TAVR).

The purpose of this public submission is to highlight:

- The key disparities and challenges that were debated at the MEDCAC meeting on 7/25/2018
- Arbitrary volume thresholds limits patients access to TAVR and expands disparities that already exist among minorities
- Potential recommendations for NCD Reconsideration

At the MEDCAC meeting on 7/25/2018, Dr. Aaron Horne presented on the key disparity challenges that exist with severe AS patients today. In particular, he highlighted the following challenges:

- One Study referenced by societies presentations reporting lower Severe AS prevalence in African Americans has significant limitations including the fact that it is not a true prevalence study based off clinically indicated echos and there was no independent assessment of echos. (1)
- Existing disparities to TAVR access among African Americans are well documented. (2, 3, 4)
- Despite the increase in referrals for TAVR, African Americans are still less likely to be referred for treatment. In fact as the number of TAVR procedures among Caucasians have grown the number of African Americans who receive TAVR remains relatively flat. (3, 5)
- Based on limited data prevalence of AS does not vary by ethnicity. (6) However, African Americans are at an increased risk for earlier onset of AS, hence become symptomatic more quickly. (7) Currently ~78,000 African Americans are at risk of Severe Aortic Stenosis in the U.S. (8)
- Under-treatment was found to be significantly higher between African Americans than other groups. Additionally, it was found that low income patients are also less likely to receive treatment - citing that for every \$1K income increase there that was a 0.9% increase in the odds of receiving TAVR. (9)
- Looking at real world results below, the TAVR Registry cites that there is a substantial treatment differences between whites and other races. (5)

54,782 US TAVR patients; small proportion of minorities treated

Variable	Level	Overall (n=54,782)	2012 (n=4,627)	2013 (n=9,052)	2014 (n=16,295)	2015 (n=24,808)
Age (yrs)	Median	83.0	84.0	84.0	83.0	83.0
Gender (%)	Male	51.7	52.6	46.9	52.6	52.7
Race (%)	White	94.0	94.3	94.2	93.8	94.1
	Black/African American	3.8	3.8	3.5	3.9	3.8
	Asian	1.1	1.1	1.3	1.3	1.0
	Hispanic or Latino Ethnicity	3.8	3.5	3.5	3.9	4.0

- When treated with TAVR, African Americans demonstrate similar outcomes to Caucasians. (10)
- Patients over the age of 65 avoid traveling for care. When presented with a 1% increased risk of death, 75% of patients would still prefer their local hospital. (11)
- Minority Medicare beneficiaries have less economic stability to overcome additional barriers to access healthcare services. Median income and saving levels for minority Medicare beneficiaries are exceedingly less than whites. Significant costs associated with travel could limiting their ability to have access to this life saving therapy. (14)
- Arbitrary volume thresholds disproportionately impact smaller community hospitals, therefore, negatively impacting minorities. (12)
- Most important, Aortic Stenosis is a deadly disease and the increased risk of mortality associated with waiting for treatment far outweighs any potential quality benefits achieved through volume thresholds. (13)
- The significant increase in volume requirements as proposed by the joint societies consensus document will either result in a significant reduction in TAVR centers (most of which are in smaller communities), or will place smaller community TAVR centers at a dangerous risk of violating CMS rules. Furthermore, as stated during the MEDCAC meeting on 7/25/2018, while the intention of the joint societies consensus document may not be to shut down lower volume sites the responsibility of managing such requirements is passed to CMS. We believe CMS should focus on expanding access and not adopting policies that could limit patient access.

We believe that the NCD reconsideration is an opportunity for CMS to not only expand patient access to TAVR among minorities, but also put forward a policy that offers all therapies (TAVR and SAVR) in an equitable manner. All AVR patients, regardless of geography, race, gender and income, deserve to have access to all forms of therapies. In addition, Medicare beneficiaries can only achieve true shared-decision making, if there is:

- A policy that addresses all therapies for AVR to provide equitable access
- The same transparent quality measure applicable to both TAVR and SAVR
- Appropriate access-level to both therapies within reasonable distance

The current NCD has resulted in the careful expansion of U.S. TAVR centers and TVT data has demonstrated a continuous improvement of outcomes in TAVR each year. However, under treatment and disparities in access remain an issue. Rather than focusing on ways to expand access in undertreated communities, the current expert consensus document recommends a significant increase in volume thresholds. From our perspective, it is unclear what evidence necessitates an urgency to significantly increase volume requirements.

In contrast, there is little to no focus, transparency or oversight on SAVR only centers. The only way to truly achieve quality improvements, is to treat both treatment options equally. In the absence of an equitable policy for both TAVR and SAVR, patients' best interest could take a back seat to any site's desire to meet certain volume requirements. Moreover, without a transparent quality standard, applicable to both TAVR and SAVR, low volume, high quality TAVR centers in smaller communities that often serve minorities will be under pressure, while there will be no oversight on SAVR only centers, regardless of their outcomes.

Significant resources have been invested to develop the TVT registry. Rather than directly measuring quality through the TVT registry, the expert consensus document relies on volume requirements as a surrogate for quality. Additionally, we still know very little about the underlying reasons for the under treatment of minorities and the TVT registry has not shed any light on this subject. If volume requirements, and not quality measures, are used to evaluate a program's status, we question the justification for the continued investment in the TVT registry, and the corresponding burden placed on sites. As an alternative, we suggest applying the resources currently dedicated to the registry to better understanding the underlying causes of under treatment, and to developing approaches to meaningfully address treatment disparities.

The new TAVR NCD will be in place for many years to come. Through robust clinical trials and exceptional outcomes data, TAVR indication has already been expanded to intermediate-risk patients, and it is expected to increase to low-risk patients in 2019. The growth of TAVR and patients' preference for less invasive options will result in a significant decrease in SAVR volume. As a result, most low volume hospitals will struggle to meet an arbitrary SAVR volume requirements.

The new NCD should prioritize equitable patient access and transparency. Shared Decision Making (SDM) should be mandated in all centers, for both SAVR and TAVR and transparent quality metrics is how programs should be differentiated. Limiting patient access through arbitrary procedure-specific quotas will create unintended barriers to TAVR for patients.

There is also opportunity for CMS to collaboratively understand and address disparities in access within minority communities. Developing a greater understanding of patient barriers and using this to increase awareness could help close the treatment gap. Protecting community TAVR centers and the patients they treat needs to be a priority. Disparities to TAVR access are well-documented and may result from multiple complex factors including socioeconomic disparities, inherent biases in healthcare provision, fewer referrals to specialists, poor cultural competency and language barriers. There are many avenues including encouraging shared physician-patient decision-making that can lessen these disparities. As we have seen, education, of both patients and physicians can be a key foundational step. The ABC is uniquely positioned to partner with CMS to develop effective initiatives on both a local and national level to increase awareness about this disease state in minority communities. A principal initiative for the partnership could be the development and provision of a nationwide CME program that will better educate physicians about the gross under-diagnosis and treatment of Aortic Stenosis in these minority communities. However, it cannot be understated that the greatest contributor to who is able to access TAVR for treatment of HVD is the current NCD, which does not support where minority patients live and receive care.

Citations:

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