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The Society
of Thoracic
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Society for Cardiovascular
Angiography & Interventions

April 25, 2019

Tamara Syrek-Jensen, JD
Director
Coverage & Analysis Group
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

RE: Proposed Decision Memo for Transcatheter Aortic Valve Replacement (TAVR)
(CAG-00430R)

Dear Ms. Syrek-Jensen:

The Society of Thoracic Surgeons (STS), the American College of Cardiology (ACC), the American Association for Thoracic Surgery (AATS), and the Society for Cardiovascular Angiography & Interventions (SCAI) are pleased to submit joint comments below on the CMS proposed decision memo for TAVR. The societies recognize the significant time and effort that produced the decision memo, including listening to feedback from the clinical community and a variety of stakeholders. We appreciate the inclusion of certain elements for which the societies advocated. It is also evident that CMS strove to balance differing interpretations of evidence that results in a decision memo rooted in pragmatic compromise. While understandable, we strongly believe this approach as it currently stands is likely to produce suboptimal patient outcomes.

We have previously conveyed our insights and recommendations to CMS in multiple venues and appreciate CMS's willingness to consider this letter in formulating the final TAVR NCD. Our comments on the draft NCD and suggested improvements are provided below with an appendix of additional background information included at the end of this letter.

Support for Continued Coverage with Evidence Development (CED)

TAVR has been the subject of CED as a new form of valve replacement and a disruptive technology. CMS has articulated the need for continuing evidence development and data collection through CED in a revised NCD for TAVR. The societies strongly support CMS's proposal to maintain the requirement for data collection through an approved registry as a mechanism to answer key questions and fill evidence gaps. The CED questions that CMS propose, and the addition of a CED question regarding morbidity and

procedure-related factors' role in patient outcomes as well as long term valve durability, performance of new, not yet approved valves and performance in low risk patients, align with the CED questions that we suggested in our comments on the national coverage analysis. The societies look forward to answering these and other questions such as the intermediate and long-term safety and efficacy of new device iterations through high quality data collection. We also remain committed to continuously improving the STS/ACC TVT Registry to optimize sites' user experience by decreasing the burden of data collection while improving TAVR standards and outcomes.

Pre-Procedure Consultation Requirements

The societies are supportive of the CMS proposal to revise the existing requirement for pre-procedure consultation with two cardiac surgeons to a requirement for pre-procedure consultation with one cardiac surgeon. The existing requirement was a carryover of pivotal clinical trials but is now commonly an obstacle to care as the technology has dispersed. The societies further affirm that patient evaluation is optimally performed jointly in a multidisciplinary valve clinic and that patient preferences with regard to surgical aortic valve replacement (SAVR) or minimally-invasive TAVR and outcomes that matter most to them be considered. The multidisciplinary valve clinic is a preferred venue for shared decision-making as opposed to separate "face to face" consultations with cardiologist and surgeon. We recommend that CMS provide clarification in coverage condition 2 by specifically noting that the pre-procedural consultation be performed by a surgeon and interventional cardiologist who are part of the heart team.

We also support the revision and updated language to include consideration of suitability for SAVR, TAVR, medical, or palliative therapy.

Finally, consistent with the 2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement,¹ the societies support the continued emphasis on joint participation in intra-procedural technical aspects of the procedure by the heart team's interventional cardiologist(s) and cardiac surgeon(s). While some interventional cardiologists may consider surgical presence as unnecessary and some cardiac surgeons may consider their presence burdensome, the professional societies remain committed to maximizing patient safety and affirm that a multidisciplinary approach meets that goal for the following reasons. First, 1-2% of TAVR procedures have potentially fatal complications of coronary occlusion, annular rupture, aortic dissection, cardiac perforation, sudden cardiogenic shock, valve embolization, and other complications that require the immediate involvement of a cardiac surgeon. Second, approximately 5%-10% of TAVR cases require alternative access that necessitates surgical skills. Finally, cardiologists and surgeons in existing TAVR programs have jointly performed many procedures and they each contribute to intra-procedure decision making and procedure performance. Since CMS has proposed relaxed requirements to start a TAVR program, hundreds of new and in all likelihood low volume programs will likely emerge as a result

¹ Bavaria JE. 2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement. J Am Coll Card 2019; 73:340-374.

of this change in requirements. To balance this change, CMS has an even greater responsibility to require the enhanced patient safety net provided by the presence of a multidisciplinary team.

Volume Requirements Inconsistent with Expert Consensus Document and New Data

CMS has proposed revisions to the procedure volume requirements for maintaining a TAVR program and opening new sites. By proposing a maintenance threshold of 50 annual aortic valve replacements (AVRs) with at least 20 of them being TAVRs, or 100 biennial AVRs with at least 40 of them being TAVRs, the proposed coverage could accelerate the trend of fewer SAVRs and more TAVRs performed in the coming years. This approach is clever in its flexibility and could be useful—if the thresholds are adjusted. Again, we are extremely concerned that the proposed volume requirements will translate into a proliferation of low volume TAVR programs at increased risk for having suboptimal outcomes.

The reduced aortic valve replacement volume requirements are inconsistent with the expert consensus document and recently published findings on the inverse association of mortality with hospital and operator TAVR volume, as well as the new data on the inverse association of mortality with hospital SAVR volume, and the major limitations in assessing TAVR and SAVR performance and outcomes when volumes are low.

The volume thresholds should be adjusted and increased for several reasons. First and most important is that newly published TVT Registry data reaffirm the rationale for the societies' prior recommendations that each center perform at least 50 TAVRs annually. The article published in the *New England Journal of Medicine*² summarized TVT Registry data from 2015 through 2017. It describes a clear relationship between hospital and operator procedural volume and 30-day risk-adjusted mortality post-TAVR. Even after the exclusion of the first 12 months of a center's TAVR procedures, mortality at 30 days was higher and more variable at hospitals with low procedural volume than at hospitals with high procedural volume. In another study using the New York Statewide Planning and Research Cooperative System data registry,³ there was a similar inverse relationship between operator volumes and in-hospital outcomes. The volume-outcomes relationship persisted even after accounting for an initial learning curve. The same volume outcome inverse relationship also exists for SAVR.

The second reason to increase the volume thresholds is that without an adequate denominator, quality measurement becomes problematic due to the statistically wide confidence limits inherent with small volumes.⁴ Some of these statistical challenges can be addressed by using rolling aggregated 3-year volume and outcomes data as is currently

² Vemulpalli S. Procedural Volume and Outcomes for Transcatheter Aortic-Valve Replacement [Internet]. N Eng J Med. 2019 [cited 2019 April 18]; Available from: <https://www.nejm.org/doi/full/10.1056/NEJMsa1901109>

³ Salemi A. Individual Operator Experience and Outcomes in Transcatheter Aortic Valve Replacement. JACC Cardiovasc Interv 2019; 14:90-97.

⁴ Dehmer GJ. Challenges of Measuring and Assuring Quality for Transcatheter Aortic Valve Replacement. J Am Coll Cardiol 2019; 73: 336-9.

done by the STS National Database in assessing SAVR outcomes. Importantly, adequate annual case volumes are needed to properly measure quality of clinical outcomes.

Third, under the new proposed volume requirements, a site could conceivably perform 50 TAVRs and zero SAVRs. This would greatly undermine the important role the cardiac surgeon plays on the structural heart team and the surgical expertise available within the institution to care for complications, conversions and non-TAVR candidates.

For all the reasons above, we argue that higher volume standards for TAVR are necessary. The same applies to SAVR volumes which are also addressed in the 2018 expert consensus document. Consistent with the 2018 expert consensus document, the societies reiterate the recommendation that optimal patient care by a site requires performance of ≥ 50 TAVR cases per year or 100 cases over 2 years. That is paired with a requirement for performance of ≥ 30 SAVRs per prior year or 60 over 2 years. Under a combined AVR approach, that would be ≥ 80 AVR cases per year with ≥ 50 of those being TAVR or ≥ 160 AVR cases over 2 years with ≥ 100 of those being TAVR.

Ensuring high quality patient care for Medicare beneficiaries is a critical mission of CMS and professional societies. We recognize that CMS grappled to find an ideal balance between center volume requirements and patient access. However, we strongly believe that there is no evidence demonstrating that a TAVR access problem exists beyond the rural and socioeconomic access issues faced across the U.S healthcare system. We provided evidence to CMS in support of this position at and after the MEDCAC. The proposed decision memo suggests that CMS has been persuaded by the “access problem” argument and that reducing the barrier to entry for new TAVR programs will facilitate more TAVR sites in rural and socioeconomically distressed areas. We expect most new TAVR sites will open in already well-served and saturated urban locations, consistent with the trend we’ve seen over the last 18 months. If CMS’s priority is to facilitate opening more sites with relaxed requirements, the societies believe it is incumbent on CMS and facilities to do more to assure optimal patient care and continuous quality improvement.

Measuring and Verifying Quality Outcomes

Data Completeness

Data completeness and data quality are essential for high fidelity quality measurement and assessing the key questions CMS seeks to answer through CED. We strongly recommend the NCD include more specifics regarding data completeness. Currently the NCD requires participation in a national registry, then goes on to list the characteristics of the registry. However, registry effectiveness is driven by completeness and accuracy of the data submitted by sites. Sites should be required to achieve certain thresholds of data completeness, as defined by the registry. This could be done by adding language to coverage condition 6 that addresses outcomes tracked by the registry. Revised language might say, “The heart team and hospital must submit required data that is complete and

accurate to a prospective, national, audited registry...” instead of requiring that they be “participating.”

Registry Based Quality Improvement Efforts

Data collected by the TVT Registry is already available and reported to sites through an online dashboard that is refreshed weekly with benchmarks re-aggregated on a quarterly basis. Hospitals can monitor outcomes and trends on a near real-time basis and drill-down to the patient level on metrics which include in-hospital mortality, significant cardiac events, bleeding events, vascular complications, quality of life metrics, and others.

Registry staff know from experience that high performing sites routinely utilize these reports to look for signals that could indicate gaps in their care and strive for continuous quality improvement. Registry staff also know that approximately 40% of sites, many of which are low-volume, do not access the patient drill-down feature on their dashboard reports.

CMS could require sites to make use of benchmark quality reports and implement quality improvement actions if persistently low performance is documented through a registry for consecutive quarters by adding language to this effect in coverage condition 5 which addresses hospital infrastructure. All sites, no matter what volume of TAVR is performed, need quality assessment and continuous quality improvement. Furthermore, the final NCD must specify mechanisms by which patients and families can have confidence that a site meets reasonable performance metrics.

Public Reporting

The TTV Registry is committed to a program of voluntary hospital public reporting and has developed the methodology and operational plan to implement. The publicly reported metrics that will be reported by the TTV Registry include commercial transfemoral TAVR volume, in-hospital risk-adjusted mortality, and 30-day risk-adjusted mortality. The public reporting program will be based on a 3-star rating system very similar to that used for SAVR and hosted on the STS website and the ACC CardioSmart website. The 3-star rating system will be implemented and validated this year with a target delivery date for public viewing of August 2020. Additional measures including a 30-day composite performance metric, quality of life, and 1-year outcomes suitable for public reporting are under development. Public reporting will be a significant incentive for sites to maintain high-quality programs and provide patients, families, and referring clinicians with objective data on site performance rather than hospital promotional marketing without objective performance metrics. CMS should incorporate a flexible requirement for public reporting that can grow with the program and public reporting capabilities.

Credentialing or Verification

Another mechanism of assuring the public that a program meets standards as outlined in the final NCD is through external programmatic review. There is precedent to CMS requiring this in the cardiovascular care arena. Credentialing requirements for sites

offering ventricular assist devices are mandated by the credentialing organization which in turn is required by CMS. CMS could require TAVR-SAVR sites to be certified by an approved credentialing organization.

Certification products are available to assist hospitals performing surgical and transcatheter valve repair and replacement. An external review and certification process that guides hospitals in meeting standards for multidisciplinary teams, formalized training, shared decision-making and registry performance could be a way for CMS to facilitate implementation of best practices and continue ensuring the high quality demonstrated under the first NCD. Hospitals participating in certification programs must participate in an established national clinical database, something the current and proposed NCDs already require. Sites that consistently underperform on quality metrics in comparison to national benchmarks would have access to quality improvement professionals and resources to assist with improvement activities under these programs.

As a tool for continuous quality improvement that aligns with the existing requirement for data collection, certification would be a low-burden mechanism for CMS to pair with the increased site flexibility it has proposed with an enhanced commitment to infrastructure and processes known to gird quality outcomes.

Recommendations for Monitoring and Reporting

The societies recommend CMS incorporate the following mechanisms in the final NCD to promote quality of care in the management of patients with aortic stenosis:

1. Sites must participate in a national clinical registry for both TAVR and SAVR that provides regular reports of a site's performance with national benchmarks.
2. Sites must meet data completeness and accuracy requirements of the registries, as discussed further below.
3. CMS should require public reporting of outcome measures as discussed above. Initially the report should include existing TAVR measures such as procedure volume and 30-day risk-adjusted mortality, with built-in flexibility to allow for incorporation of a risk-adjusted, composite quality metric that can supplant volume as a surrogate for quality.

This could be accomplished flexibly by adding a requirement to coverage condition 5. “d. The heart team and hospital publicly report TAVR procedure volume and at least one other outcome measure.”

Additional details of the program planned by the TVT Registry described above follow in the Appendix.

4. An external certification process for TAVR-SAVR programs should be identified as a mechanism any site can use to verify infrastructure and quality standards, and that underperforming sites would find useful to improve outcomes.

If CMS needs to reissue a proposed decision memo with an additional comment period to achieve this end, it would be preferable to going through the entire process of reconsidering the NCD again in the relative short term.

Shared Decision-Making (SDM)

A fundamental principle of optimizing decisions and making recommendations is that patient evaluation should be performed jointly in a multidisciplinary valve clinic, as recommended in the draft NCD. Patient preferences with regard to SAVR or minimally-invasive TAVR should be incorporated in a shared decision-making process. This was well described and supported in the expert consensus document.

The societies appreciate CMS's sensitivity about creating a requirement that cannot be met. Further, the societies have been cautious about recommending use of a specific SDM tool. The societies strongly support *a shared decision-making process* in the expert consensus document. Adding, “through a shared decision-making process,” at the end of the second sentence in coverage condition 3 would appropriately emphasize the role of SDM.

Clarifying Items

Initial Facility TAVR Experience

Similar to the existing NCD, the proposed Decision Memo would require that a new site deploy a comprehensive heart team approach that includes at least two cardiovascular surgeons and at least one interventional cardiologist who have experience with procedures related to TAVR. However, in the draft proposal, it is not necessary for any of the members of the team to have experience actually performing a TAVR. A requirement does exist for the interventional cardiologist to complete manufacturer-required device specific training. We believe the cardiothoracic surgeons should also undergo device specific training as they currently do. That requirement should be added as item b. under the surgeon requirements. Second, even at a new site, some amount of TAVR experience should be required. The 2018 expert consensus document recommends a TAVR proceduralist—which could be either a cardiothoracic surgeon or interventional cardiologist—at a new program have experience participating in 100 transfemoral TAVRs lifetime, with 50 of those serving as the primary operator. At a minimum, there should be some requirement for performance of TAVR as a primary operator in addition to device specific training. Requiring no prior TAVR experience is inadequate and inappropriate given that there are more than 600 sites and >2,000 operators currently performing TAVR.

Outcome Measures

During discussion of a possible future role for outcome measures instead of procedural volume requirements, CMS states, “We are also proposing that outcome measure results be made public.” We infer that CMS is referencing the existing requirement in clinical study criterion k. that “results must be made public within 12 months of the study’s primary completion date.” This would be different than the public reporting program the societies discussed above. It does not appear that CMS intended to propose a more ambitious program of public reporting a la Hospital Compare or a star rating system.

However, CMS does propose that CED question iv. must be addressed through a composite metric. Since the only composite metric of which the societies are aware is the one being developed by STS and ACC for 30-day mortality-morbidity, it would seem that is the metric to which CMS is referring. It would be helpful for CMS to provide clarification on this matter in the final decision memorandum.

Summary

Thank you for considering these comments as you and your team work through the NCD process. To summarize:

1. The societies support continued CED to answer outstanding clinical questions.
2. The societies support revising the two-surgeon pre-procedure consultation requirement to a heart team consultative requirement that includes one surgeon and one interventional cardiologist.
3. The societies recommend that CMS revise the volume requirements to reflect the most current literature showing improved outcomes at sites that perform at least 50 TAVRs annually.
4. If CMS does not revise volume requirements, it should move expeditiously toward a system that where outcome measures replace volume requirements. Public reporting of procedure volume and at least one significant outcome measure, e.g., 30-day risk adjusted mortality aggregated over 3 years, should be required.
5. Sites may participate in an external certification process, as described above.

Please contact James Vavricek at jvavricek@acc.org should you need any additional

information in follow-up to these comments. We look forward to the final NCD and continuing to work with CMS to ensure patients have access to high-quality aortic valve therapies.

Sincerely,

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David Cox, MD, FSCAI
SCAI President

David R. Jones

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Robert S.D. Higgins

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Appendix

Background

This draft NCD addresses TAVR program requirements, but there are several clinical and broader perspectives we wish to communicate to CMS as an important clinical overview and structural context which informed our specific comments and recommendations for modifications of the draft NCD.

- The NCD is a regulatory and coverage document but it also outlines aspects directly impacting on the clinical management of patients with aortic stenosis. Thus, guidance from professional medical societies is essential to produce a final NCD that is solidly grounded on a robust evidence base built from decades of clinical experience and clinical trials in order to optimize the care of patients.
- This NCD has broader implications than just TAVR. This NCD establishes a precedent regarding the distribution and organization of centers involved with treating patients with valvular heart disease as transcatheter and surgical therapies rapidly evolve.
- TAVR has become an established method of replacing the stenotic aortic valve. In fact, in 2017 TAVR was performed more commonly than surgical aortic valve replacement (SAVR) in the US. Two recently published trials show equivalency and, in one trial, superiority of TAVR to SAVR in selected patients at low risk for SAVR. These trials, followed by expected FDA expansion of TAVR indications, set the stage for the next major clinical transformation in patient care. The final NCD must provide structure and requirements to monitor this transformation and optimize the quality of care.
- Our broader clinical and patient-centric perspective make it essential for evidence development and data collection beyond TAVR to the overall management of aortic valve disease, including its prevention, and the rapidly evolving roles of both modalities of aortic valve replacement, TAVR and SAVR. SAVR, while not the subject of an NCD and thus not regulated in the same fashion as TAVR, is also undergoing a major realignment as to when it should be considered to treat aortic valve disease and it remains the best treatment for some patients. Furthermore, the need to routinely assess SAVR outcomes beyond the 30-day post-operative period and to gather patient-reported outcomes including quality of life after SAVR are now apparent as we apply these same yard-sticks to TAVR and face the increasing need to provide clinicians and patients with similar datasets on SAVR and TAVR to make informed choices.
- With the aging of the American population we are now faced with the emergence of a major public health issue from degenerative valvular heart disease effecting an increasing percentage of the population. In addition, the management challenges in the large pool of patients who have previously had surgical aortic valve replacements with a tissue valve have emerged. Structural deterioration of tissue valves necessitates considering either surgical redo or transcatheter valve-in-valve. TAVR, also a tissue valve, is now being performed in patients with life

- expectancies exceeding 10 years, and therefore we foresee a similar post-TAVR management challenge growing in frequency over the next decade.
- We share with CMS' perspective that to achieve the goals for health care in the United States requires consideration of both reasonable access to care and a high quality of care including all domains of quality as articulated by the Institute of Medicine.
 - Furthermore, the rising costs of health care require careful planning in preventing excessive redundancy of facilities and services, inappropriate utilization, disproportionately high pricing of medical devices in the US, and waste especially of high-technology and expensive facilities and services such as needed for heart valve replacement
 - Regulatory decisions, such as the final NCD, as well as routine patient management, must be based on robust scientific evidence, the needs of patients, and carefully avoid biases, political pressures, and various forms of conflicts of interest.

TVT Registry Public Reporting Program Outline

- The 30-day risk adjusted mortality metric will be reported to the sites. This is reported as an Observed/Expected ratio. This will be available for public reporting by 2020. Sites will be required to meet a data completeness threshold level in order to qualify for the TAVR 30-day risk adjusted mortality measure.
- A 30-day Composite Outcome metric that will include Death, Stroke, Major Bleeding, AKI, Paravalvular leak has been developed. These metrics are being chosen as they are empirically based on their contribution to late (1 year) mortality and patient reported health status (KCCQ). This quality metric will be implemented this year, validated and available for hospital review in 2020 and publicly reported in 2021. Sites will be required to meet a data completeness threshold level in order to qualify for the TAVR Composite Quality measure. The composite metric is superior for public reporting because in medical procedures where there is low mortality it allows greater ability to discriminate differences in quality between centers.
- The Composite metric would be sent to the sites as a “Star Rating” where one- and three-star sites are statistically worse or better than expected.
- CMS can also support the transition to the 3-star rating system when it has gone through the steps outlined above. Subsequently, the reporting of one-year outcomes including quality of life data should be encouraged.