Transcatheter aortic valve replacement for prime time unrestricted distribution? Not so fast, my friend

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The new “2018 AATS/ACC/SCAI/STS Expert Consensus Systems of Care Document: Operator and Institutional Recommendations and Requirements for Transcatheter Aortic Valve Replacement”¹ in this issue of the *Journal* was written as an update to the original 2012 document because of the rapidly changing landscape for transcatheter aortic valve replacement (TAVR) therapy.

The original national coverage decision document (NCD) was based on coverage with evidence development and the institution of the Society of Thoracic Surgeons and American College of Cardiology TVT National Registry with mandatory requirement for submission of all commercial TAVR data to the registry. It also had site and operator requirements to promote optimal patient outcomes after commercial release. In 2017, more than 50,000 patients received commercial TAVR at 582 sites, with no major proven TAVR access issues and TAVR outcomes that paralleled those achieved in the US Food and Drug Administration clinical trials.² Rational dispersion of TAVR was therefore achieved with the original 2012 NCD.

This updated version of the multisociety expert consensus document is necessary to reflect the changing landscape for TAVR: advanced devices, improved procedural techniques, and dispersion of active sites. A primary objective for this version is to provide guidance to help centers achieve high-quality outcomes for all aortic stenosis (AS) treatment options. The basis for operator and institutional requirements is a balance between patient access to care and patient safety. This document reaffirms a multidisciplinary team approach for patient selection, reaffirms commitment to high-quality care, and introduces shared decision making with patient preference in mind.

Quality outcomes metrics are the cornerstone of this document.¹ The document proposes creation of composite models, including 1-year risk adjusted outcome for mortality and quality of life, which requires continuation

TAVR distribution mimics population, demonstrating rational distribution of TAVR access.

Central Message

The continuation of the national coverage decision document for TAVR is necessary to ensure quality patient outcomes and understand more fully the roles for TAVR and SAVR in aortic stenosis therapy.

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of mandatory submission of all essential data to the TVT Registry. Data will be analyzed and nationally benchmarked with site and public reporting. Sites can compare their quality of care with respect to all programs, determine areas for augmentation, and initiate internal and external mechanisms for improvement.

A volume requirement is established within the new document to minimize the inherent uncertainty and unreliability of small sample size estimates that hamper the capabilities of statistical power to detect outliers. A previous publication that was based on TVT data supported the volume-outcome relationship in TAVR,³ and an updated preliminary version verifies the continuing relationship even within the changing therapy landscape.⁴

The continuation of the NCD is essential in resolving unanswered initial questions as well as new questions that arise as TAVR indications expand. One-year composite risk-adjusted outcomes for mortality and quality of life are necessary to determine proper patient selection of those who will truly benefit from the nonsurgical and high-risk candidate groups. Outcome analyses of the impact of TAVR from the recently approved moderate-risk patients and the ongoing low-risk trial candidates, and characterization of future indications for TAVR such as symptomatic moderate-risk AS, moderate- and low-risk TAV and SAV patients with bicuspid AS are essential.

TAVR is *not* ready for prime time unrestricted distribution, the multidisciplinary team is essential as management of AS evolves, and continuation of the NCD for TAVR is necessary to ensure quality patient outcomes and more fully understand the roles for TAVR and SAVR in AS therapy.

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