Expanding Access to Transcatheter Aortic Valve Replacement (TAVR)

For patients diagnosed with severe symptomatic aortic stenosis (AS), open-heart surgical replacement of the aortic valve (SAVR) was previously the only available definitive treatment to reduce symptoms and extend life. Over the past decade, transcatheter aortic valve replacement (TAVR) has emerged as a minimally invasive alternative to surgery. TAVR is now the primary therapy for inoperable patients and is rapidly replacing SAVR for patients at high or intermediate risk for surgery.1–4

The aortic valve is the gatekeeper that allows oxygenated blood to flow from the heart to the rest of the body. Narrowing of the aortic valve, called aortic stenosis (AS), disrupts this flow of blood, leading to episodes of chest pain, loss of consciousness, and heart failure.

In 2019, the U.S. Food and Drug Administration approved TAVR for use in patients with severe symptomatic AS at low surgical risk.12 Consequently, the Centers for Medicare and Medicaid Services relaxed its national coverage rules, lowering cardiac surgical volume requirements in order to expand the number of hospitals providing the procedure.13

Takeaways from our research *
A University of Michigan research team studied hospitals that were not providing TAVR before the Medicare coverage changes, to assess how many of these hospitals may now meet the new surgical volume requirements and to describe their characteristics, using national Medicare data.

The number of hospitals eligible to provide TAVR could **double** under new Medicare coverage rules.

Sites newly eligible to provide TAVR are more likely to have fewer beds, be non-teaching hospitals, and treat less medically complex patients.

Variation in the geographic distribution of TAVR hospitals persists, with limited access to TAVR in rural and safety net hospitals.

What are the implications for policy and practice?
As access to TAVR is expanded to new sites, important considerations remain in order to help ensure optimal outcomes for patients.

- TAVR-specific quality metrics are needed in order to monitor patient outcomes as access expands. Quality metrics should be evaluated to ensure that they are valid and reliable.
- The volume of TAVR procedures at the new and existing sites should be monitored, with special consideration around how to measure patient outcomes for sites with a low volume of TAVR procedures. Evidence shows that outcomes at low volume sites are worse on average, compared to high volume centers.14
- The location and characteristics of TAVR and non-TAVR hospitals should be monitored to help ensure that access is expanded in areas of need, rather than expanding further in existing markets.
- Continued tracking of case volume and quality for cardiovascular procedures outlined in national coverage requirements is needed to mitigate potential unintended effects.

**Aortic Stenosis in the U.S.**

| 1 in 8 adults age 75 and older have moderate or severe AS. 5–7 | 50% mortality rate within 2 years of severe symptomatic AS diagnosis if untreated. 8–10 | 7-fold increase in the volume of TAVR procedures between 2012 and 2016. 11 |

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**Referenced study**

Additional references


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To download this brief, visit: ihpi.umich.edu/TAVR

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