



# Effective Health Care

## Transcatheter Aortic Valve Replacement Nomination Summary Document

### Results of Topic Selection Process & Next Steps

- The topic area, *Transcatheter Aortic Valve Replacement*, was found to be addressed by an evidence-based guideline from the American Heart Association (AHA) and the American College of Cardiology (ACC). The guideline focuses on the management of patients with valvular heart disease. Given that the existing guideline addresses this nomination, no further activity will be undertaken on this topic.
  - Nishimura, RA et al. (2014). 2014 AHA/ACC Guideline for the Management of Patients With Valvular Heart Disease: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. *J Am Coll Cardiol.* 2014;63(22):e57-e185.

### Topic Description

**Nominator(s):** Organization

**Nomination Summary:** This topic was nominated by a stakeholder panel, which included healthcare providers, members of professional societies, representatives from Federal agencies, private insurers, and patient advocacy groups.

The stakeholder panel identified the safety and effectiveness of transcatheter aortic valve repair (TAVR) as an area of significant morbidity, mortality, and variation in utilization. The panel also cited that more information pertaining to TAVR in subgroups such as patients with heart failure, those patients deemed not candidates for surgical aortic valve replacement, women vs. men, and elderly patients were of particular interest. A systematic review on this topic could inform practice and guideline development, and improve the quality of care by reducing morbidity, mortality, and costs.

**Staff-Generated PICO**

**Population(s):** Patients with severe aortic stenosis

**Intervention(s):** Transcatheter aortic valve repair (TAVR)

**Comparator(s):** Aortic valve surgery, medical therapy

**Outcome(s):** All-cause mortality, major vascular events, stroke, transient ischemic attacks (TIAs), acute kidney injury, repeat aortic valve procedures, and quality of life (QoL)

**Key Questions from Nominator:** How do we determine the comparative safety and effectiveness of transcatheter aortic valve replacement in patients with heart failure and within specific high-risk subgroups of interest?

## Considerations

- Aortic valve stenosis is a form of heart disease in which the valve that regulates the flow of blood from the heart is prevented from opening fully. When the leaflets do not fully open, the heart must work harder to push blood through the narrowed valve. Eventually, the heart's muscles weaken, increasing the risk of heart failure. Risk factors for aortic valve stenosis include congenital valvular disease, history of rheumatic fever, and old age (65 and older).
- Up to 1.5 million people in the US have aortic stenosis, approximately one-third of whom have severe aortic stenosis. About 250,000 individuals with severe aortic stenosis are symptomatic. Individuals with severe symptoms may need surgical treatment.
- Aortic valve stenosis may be treated surgically by replacing the faulty valve. However, some patients are not candidates for this procedure because they are not healthy enough for open-heart surgery.
- Transcatheter aortic valve repair (TAVR) is a newer alternative to traditional surgical treatment of severe aortic valve stenosis. It is less invasive, and could be an option for individuals who are not healthy enough for open-heart surgery.
- This topic area was found to be addressed by a 2014 guideline from the American Heart Association (AHA) and the American College of Cardiology (ACC) for the management of people with valvular heart disease. The guideline recommends that surgical aortic valve replacement (AVR) remain the intervention of choice for patients with an indication for AVR and low or intermediate operative risk. For individuals with high surgical risk, TAVR is a reasonable alternative to surgical AVR. For patients with prohibitive surgical risk, TAVR is recommended surgical treatment.