

# NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

## Late Stage Assessment

### Transcatheter heart valves for transcatheter aortic valve implantation in people with aortic stenosis

#### Final scope

##### Remit/evaluation objective

To assess the incremental clinical, economic and non-clinical benefits of transcatheter aortic valve implantation devices for people with severe aortic stenosis to justify price variation and inform procurement decisions.

##### Background

Aortic stenosis occurs when the aortic valve thickens or stiffens and doesn't open properly. Extra force is needed to pump blood through the valve, which puts strain on the heart. A recent study has estimated the overall prevalence of severe aortic stenosis among people over 55 years in the UK to be almost 1.5%, equal to around 300,000 people living with the condition at any one time.<sup>1</sup> Among those people, just under 200,000 were estimated to have symptomatic disease, which would require treatment. However, the system is severely strained. During the COVID-19 pandemic, cardiac surgery was limited to emergency cases. As a result, by March 2023 there were more than 380,000 people on cardiac waiting lists.<sup>2</sup> Long waiting times are a significant issue, because they have a negative impact on clinical outcomes.<sup>3,4</sup> Furthermore, the prevalence of aortic stenosis is projected to increase in the upcoming years as the British population ages.<sup>5</sup> People with aortic stenosis often have comorbidities, such as hypertension, coronary disease, atrial fibrillation, and renal dysfunction.

##### Current care pathway

For people with severe aortic stenosis the diseased valve can be replaced. Replacement of the aortic valve can be by either surgery or transcatheter intervention. Decision-making about the most appropriate intervention happens at a multidisciplinary team meeting. Medical history, treatment wait times, and planning for future interventions are considered. Transcatheter Aortic Valve Implantation (TAVI) is a minimally invasive procedure that avoids the need for a cardiopulmonary bypass and sternotomy. It involves the implantation of an artificial aortic valve, which is passed through a catheter inserted in a blood vessel in the upper leg or chest. TAVI is recommended for people who are at high surgical risk or if surgery is unsuitable ([NICE guideline 208](#), [NICE interventional procedure guidance 586](#)). In February 2023, NHS England published a position statement that to alleviate the pressures on local systems, TAVI should also be considered as a treatment option for eligible people at an intermediate and low-surgical risk ([NHS England, 2023](#)). TAVI is also recommended as a less invasive treatment option if a previous

bioprosthetic valve has failed ([NICE interventional procedure guidance 653](#)). This procedure is referred to as valve-in-valve (ViV) TAVI.

The 2021 GIRFT National Cardiology Report has recommended the reorganisation of valve disease services ([NHS England, 2021](#)). A number of optimisation measures for aortic valve disease services have been implemented across the NHS. These include the use of local anaesthesia with sedation in the vast majority of procedures, a move towards preferentially using the transfemoral route, making refinements in the delivery equipment, having a single point of contact to co-ordinate patient care and consideration of same day discharge when appropriate. TAVI performed under local anaesthesia with sedation has comparable patient outcomes to those done under general anaesthetic.<sup>6</sup> Pre-procedural assessment and the TAVI procedure are done in highly-specialised heart valve clinics. Recent research has shown that shifting the pre-procedural workup to a local centre has the potential to significantly reduce wait times for TAVI.<sup>7</sup>

### **Population**

TAVI is recommended for people with severe aortic stenosis who are at high surgical risk or for whom surgery is unsuitable ([NICE guideline 208](#)). People with severe aortic stenosis who are at low or intermediate surgical risk should also be considered for TAVI ([NHS England, 2023](#)).

### **The technology**

An artificial aortic valve is implanted during a TAVI procedure. The device comprises of an expandable stent frame that suspends animal tissue leaflets.<sup>8</sup> The leaflets can be bovine or porcine and can have intra-annular or supra-annular position. The position may influence the hemodynamics of the valve and may impact future heart treatment. The stent frame can be made from a cobalt-chromium or a nickel-titanium (Nitinol) alloy. The valve is passed through a catheter and when positioned it can expand autonomously (self-expanding valve) or using a balloon in the catheter tip. TAVI devices come in different sizes, ranging from 20mm to 34mm.

### **Incremental innovations**

Innovative features have been added to newer generation devices. These include the availability of smaller delivery sheaths, advances in deployment and anchoring and the ability to reposition or recapture a device in a case of suboptimal positioning. Newer devices also offer the opportunity to preserve coronary access, a range of sizes and specific designs to improve valve hemodynamics and procedural specification.

The following TAVI devices will be included in this assessment:

- Acurate Neo2 (Boston Scientific)
- Allegra (Biosensors)
- Evolut R, Evolut Pro+, Evolut FX (Medtronic)
- Hydra (SMT)

- Myval Octacor (Meril)
- Navitor (Abbott)
- Sapien 3, Sapien 3 Ultra (Edwards Lifesciences)
- Trilogy (Jenavalve).

<b>Intervention</b>	Transcatheter heart valve for Transcatheter Aortic Valve Implantation (TAVI)
<b>Population</b>	Adults with symptomatic severe aortic stenosis who have been identified as suitable for valve replacement
<b>Subgroups</b>	<p>The following subgroups will be considered:</p> <ul style="list-style-type: none"> <li>• People who are at high surgical risk or for whom surgery is unsuitable</li> <li>• People who are at low surgical risk</li> <li>• People who are at intermediate surgical risk</li> <li>• People with a failed previous bioprosthetic valve.</li> </ul>
<b>Comparators</b>	Heart valve for Surgical Aortic Valve Replacement (SAVR) Alternative transcatheter heart valves for Transcatheter Aortic Valve Implantation (TAVI)
<b>Outcomes</b>	<p>Clinical outcome measures relevant to the comparison with SAVR or alternative TAVI, can include but are not limited to:</p> <ul style="list-style-type: none"> <li>• mortality</li> <li>• length of hospital stay, including ICU stay</li> <li>• reintervention rate</li> <li>• heart failure</li> <li>• stroke</li> <li>• vascular complications</li> <li>• atrial fibrillation</li> <li>• acute kidney injury</li> <li>• endocarditis</li> <li>• pacemaker implantation rate</li> <li>• paravalvular leak</li> <li>• conversion to surgery</li> <li>• health-related quality of life.</li> </ul> <p>User preference and non-clinical outcome measures will be based on the prioritisation of outcomes as part of the multi-criteria decision analysis.</p>

<p><b>Economic analysis</b></p>	<p>The economic analysis will inform the benchmark price and the additional value of the incremental differences between the available technologies.</p> <p>The economic analysis will be based on the health economic model developed for NICE Guideline 208. Any analyses will be in accordance with the NICE reference case:</p> <ul style="list-style-type: none"> <li>• Time horizon of sufficient length to reflect all important differences in costs or outcomes between the technologies being compared</li> <li>• Costs will include the cost of the technology, accessories, training, staff and any treatment or (post)-procedural costs, including capacity constraints; costs will be considered from an NHS and Personal Social Services perspective.</li> </ul>
<p><b>Other considerations</b></p>	<p>The separation of transcatheter heart valves into discrete categories, for example, with regards to the mechanism of expansion or indication, will be considered where appropriate.</p> <p>Assessment of TAVIs available to the NHS will include the value of innovative features of individual TAVIs as part of the comparison of alternative TAVIs. The impact of incremental innovations of TAVIs on access to care, treatment options, capacity and waiting lists, and the clinical care pathway may be considered as part of the comparison of alternative TAVIs.</p> <p>The prevalence of aortic stenosis rises with age. The associated mortality is also higher in older age groups.</p> <p>There may be sex-related differences in the prevalence, pathophysiology and natural history of aortic stenosis and the clinical outcomes of treatment.</p> <p>Geographical inequalities with regards to access to heart valve clinics exist.</p> <p>Cultural preferences and religious beliefs may influence the acceptability of some devices in certain societal groups.</p>
<p><b>Related NICE guidance</b></p>	<p><b>Related NICE guidelines:</b></p> <p>Heart valve disease presenting in adults: investigation and management (2021) <a href="#">NICE guideline 208</a>.</p> <p><b>Related interventional procedures:</b></p> <p>Transcatheter aortic valve implantation for aortic stenosis (2017) <a href="#">NICE interventional procedures guidance 586</a></p> <p>Sutureless aortic valve replacement for aortic stenosis (2018) <a href="#">NICE interventional procedures guidance 624</a></p> <p>Balloon valvuloplasty for aortic valve stenosis in adults and children (2004) <a href="#">NICE interventional procedures guidance 78</a></p> <p>Valve-in-valve TAVI for aortic bioprosthetic valve dysfunction (2019) <a href="#">NICE interventional procedures guidance 653</a></p>

	<p>Percutaneous insertion of a cerebral protection device to prevent cerebral embolism during TAVI (2019) <a href="#">Interventional procedures guidance 650</a></p> <p>Aortic valve reconstruction with glutaraldehyde-treated autologous pericardium for aortic valve disease (2023) <a href="#">Interventional procedures guidance 769</a></p>
<p><b>Related National Policy</b></p>	<p>NHS England (2023) <a href="#">Position Statement on Transcatheter Aortic Valve Implantation (TAVI) and Surgical Aortic Valve Replacement (SAVR) for symptomatic, severe aortic stenosis (adults) to support elective performance</a></p> <p>NHS England (2021) <a href="#">GIRFT Programme National Specialty Report</a></p> <p>South Tees NHS Foundation Trust (2023) <a href="#">Optimising the Transcatheter Aortic Valve Implantation Pathway: a delivery guide</a></p> <p>NHS England (2022) <a href="#">Delivery Plan for Tackling the COVID-19 Backlog of Elective Care</a></p> <p>The NHS Long Term Plan (2019) <a href="#">NHS Long Term Plan</a></p> <p>Department of Health and Social Care (2016) <a href="#">NHS Outcomes Framework 2016-2017: Domains 1,2</a></p> <p>Department of Health and Social Care (2023) <a href="#">Major Conditions Strategy</a> (in development)</p>

## References

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