NICE National Institute for Health and Care Excellence

NICE guidance

Transcatheter heart valves for transcatheter aortic valve implantation to treat aortic stenosis: late-stage assessment

HealthTech guidance
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This guidance replaces HTE31.

1 Recommendations

1.1 There is not enough evidence to determine whether price variation is justified between different transcatheter heart valves for transcatheter aortic valve implantation (TAVI) in adults with aortic stenosis.

1.2 NHS trusts should provide access to a range of transcatheter heart valves, so that a clinically appropriate valve is available for everyone with aortic stenosis having TAVI.

1.3 If more than one transcatheter heart valve is clinically appropriate, use the least expensive valve.

1.4 Details of everyone having the procedure should be entered into the UK TAVI registry managed by the National Institute for Cardiovascular Outcomes Research. Contact nicor.auditenquiries@nhs.net for details.

What information is needed

More information is needed to determine whether price variation between different transcatheter heart valves can be justified. This can be from primary studies or secondary analyses of real-world data sources, such as the UK TAVI registry.

Key outcomes and information that should be captured include:

- mortality
- stroke
- paravalvular leak or aortic regurgitation
- permanent pacemaker implantation
- reintervention

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- resource use including for treatment and length of stay
- the specific valve used
- the person's surgical risk.

All studies and analyses of real-world data should adjust for a range of confounding factors including the:

- impact of anatomical characteristics of the valve being replaced
- impact of calcium around the valve
- person's age, sex, ethnicity and medical history.

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What this means in practice

Considerations for procurement and commissioning

- The number of TAVI procedures done annually is rising (NICOR UK TAVI registry 2024 summary report). So, it is important that the NHS ensures the best value for money when buying transcatheter heart valves.
- 'Added value' agreements between companies and the NHS Supply Chain allow for part of the cost of a valve to be returned to the NHS or to an NHS trust based on the number of valves purchased. Even after accounting for 'added value' agreements, the NHS may benefit more from negotiating lower list prices. This is because 'added value' agreements may not release resources for the NHS.

Considerations for healthcare professionals

- When choosing a clinically appropriate transcatheter heart valve, consider the anatomy and characteristics of the valve being replaced, as well as the person's age, comorbidities and other factors that can make a particular valve more suitable. Also consider the preferences of the person with aortic stenosis when choosing which transcatheter heart valve to use, and follow the principles in NICE's guidance on shared decision making.
- Healthcare professionals should work with commissioners and procurement specialists in their NHS trust to ensure access to a range of clinically appropriate valves and to understand the relative costs of the valves. Consider emerging evidence in these discussions.

Why the committee made these recommendations

Transcatheter heart valves are used to replace a narrowed aortic valve or a failed bioprosthetic valve in people with aortic stenosis. There are many transcatheter heart valves available, which vary in features and cost. This assessment aimed to determine whether the differences in clinical, economic and non-clinical outcomes attributed to different valves could justify price variation.

For many people with aortic stenosis, several of the available valves could be used. For

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some people, a specific valve may be more appropriate. The effectiveness of individual valves is likely to depend on both the features of the valve and the characteristics of the person with aortic stenosis.

Analyses of real-world data from the UK TAVI registry are limited because of unrecorded confounders (factors that may affect the results), missing data and short follow up. There is no high-quality published evidence that is as relevant to the UK population as the TAVI registry data. The results from an economic evaluation based on real-world data analyses in the UK are too uncertain to determine whether the differences in cost between valves are justified.

More evidence is needed to show whether differences in price between valves can be justified by differences in effectiveness. If a new valve costs more, this should be justified with evidence showing that it works better than existing valves. Evidence needs to be comparative and adjust for baseline characteristics that have a large impact on outcomes. These baseline characteristics should also be recorded in the UK TAVI registry. This is to ensure that results reflect how well the valve works and not the characteristics of the people it is used in.

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2 The technologies

2.1 Transcatheter heart valves are used for transcatheter aortic valve implantation (TAVI) procedures. This is when a narrowed native aortic valve or a failed bioprosthetic valve is replaced through a blood vessel in the leg or chest. Transcatheter heart valves consist of a stent frame and animal pericardium tissue leaflets. The valves vary in:

- physical characteristics such as the:
  - alloy of the frame
  - type of tissue of the leaflet
  - available valve sizes
- technical characteristics such as the:
  - expansion mechanism
  - presence of locators or anchors
  - valve positioning relative to the native aortic valve.

    Transcatheter heart valves are used with a loading and a delivery system. The delivery system can vary in:

    - its ability to recapture and reposition the valve
    - the flexibility of the delivery sheath
    - the minimum vessel size for access.

Available valves

2.2 Ten transcatheter heart valves were available on the NHS Supply Chain and included in this assessment at the time of publication. All of them had valid CE certification as class 3 implantable devices. The ACURATE neo2 transcatheter

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heart valve (Boston Scientific) was removed from this late-stage assessment because it is no longer available in the NHS.

Allegra (Biosensors)

2.3 Allegra is a self-expanding transcatheter heart valve made from bovine pericardial tissue. It is positioned supra-annularly and is available in 3 sizes: 23 mm, 27 mm and 31 mm. It is indicated for:

- severe calcified aortic valve stenosis in people at high surgical risk
- treating severe calcified aortic valve stenosis in people with symptomatic degeneration of an aortic valve bioprosthesis.

Evolut R, Evolut Pro+ and Evolut FX (Medtronic)

2.4 Evolut R, Evolut Pro+ and Evolut FX are self-expanding transcatheter heart valves made from porcine pericardial tissue. They are positioned supra-annularly and are available in 4 sizes: 23 mm, 26 mm, 29 mm and 34 mm. The valves are indicated for severe native aortic valve stenosis. In severe native bicuspid aortic valve stenosis, the valves are indicated for

- people at intermediate or greater risk for surgical aortic valve replacement (SAVR), or
- when there is a documented heart-team agreement of risk for SAVR because of frailty or comorbidities.

  Intermediate risk is defined as the Society of Thoracic Surgeons (STS) operative risk score of 4% and above. For people presenting at low risk for SAVR (less than 4%), the valves are indicated for people 70 years and over with a left ventricular ejection fraction above 30%. The valves are also indicated for people with a stenosed, insufficient, or combined bioprosthetic valve failure needing valve replacement:

- who are at high or greater risk for SAVR, or

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- when there is a documented heart-team agreement of risk for SAVR because of frailty or comorbidities.

  High risk is defined as an STS operative risk score of 8% and above. All valves are indicated for surgical bioprosthetic valve replacement, and the Pro+ and FX are also indicated for transcatheter bioprosthetic valve replacement.

  Compared with the Evolut R, the Evolut Pro+ has an additional external pericardial wrap and an updated delivery system. Compared with the Evolut Pro+, the Evolut FX has additional gold markers to visualise implant depth and coronary alignment, and an updated delivery system. There have been no changes to the valve housing or leaflets as the design has progressed from Evolut R to Evolut FX.

Hydra (SMT)

2.5 Hydra is a self-expanding transcatheter heart valve made from bovine pericardial tissue. It is positioned supra-annularly and is available in 3 sizes: 22 mm, 26 mm and 30 mm. It is indicated for severe degenerative aortic stenosis in people with a high predictable operative mortality risk for SAVR. The decision is based on the clinical judgement of the heart team.

Myval Octacor (Meril)

2.6 Myval Octacor is a balloon-expanding transcatheter heart valve made from bovine pericardial tissue. It is positioned intra-annularly and is available in 9 sizes between 20 mm and 32 mm. Myval Octacor is indicated for aortic stenosis in people with symptomatic heart disease because of severe native calcific aortic stenosis as judged by a heart team, including a cardiac surgeon. It is also indicated for people who have a risk for open heart surgery (an STS operative risk score of 4% and above risk of mortality at 30 days).

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Navitor (Abbott)

2.7 Navitor is a self-expanding transcatheter heart valve made from bovine pericardial tissue. It is the only self-expanding valve with intra-annular leaflets. Navitor is available in 4 sizes: 23 mm, 25 mm, 27 mm and 29 mm. It is indicated for symptomatic severe native aortic stenosis in people who are considered to have a high or extreme risk for SAVR.

Sapien 3 and Sapien 3 Ultra (Edwards)

2.8 Sapien 3 and Sapien 3 Ultra are balloon-expanding transcatheter heart valves made from bovine pericardial tissue. They are positioned intra-annularly and are available in 20 mm, 23 mm and 26 mm sizes. Sapien 3 is also available in a 29 mm size. The valves are indicated for heart disease because of native calcific aortic stenosis in people at any or all levels of surgical risk. They are also indicated for symptomatic heart disease caused by failure (stenosed, insufficient, or combined) of an aortic transcatheter bioprosthetic or a surgical bioprosthetic aortic valve when a heart team, including a cardiac surgeon, considers the person to be at high or greater risk for open surgical treatments. High or greater risk is defined as a predicted risk of surgical mortality of 8% and above at 30 days, based on the STS risk score and other clinical comorbidities unmeasured by the STS risk calculator. Compared with the Sapien 3, the Sapien 3 Ultra has an augmented outer skirt.

Trilogy (Jenavalve)

2.9 Trilogy is a self-expanding transcatheter heart valve made from porcine pericardial tissue. It is positioned supra-annularly and is available in 3 sizes: 23 mm, 25 mm and 27 mm. Trilogy is indicated for native symptomatic, severe aortic regurgitation or symptomatic, severe aortic stenosis in people who have a heart team, including a cardiac surgeon, considered to have high or greater risk for SAVR. High or greater risk is defined as a predicted risk of surgical mortality of 8% and above at 30 days, based on the STS risk score and other clinical comorbidities unmeasured by the STS risk calculator.

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3 Committee discussion

The advisory committee considered evidence from several sources on transcatheter heart valves for transcatheter aortic valve implantation (TAVI) in people with aortic stenosis. The clinical evidence included analyses of real-world UK data, a systematic review and several targeted reviews of the published literature, company submissions and stakeholder responses to public consultations. The committee also considered the economic evidence from a review of the published literature and an economic evaluation done by the external assessment group (EAG), and a user preference assessment done by NICE. Full details are available in the project documents for this guidance.

The condition

3.1 Aortic stenosis happens when the aortic valve thickens or stiffens and does not open properly. The prevalence among people over 55 years in the UK is about 1.5% (Strange et al. 2022). Aortic stenosis can lead to heart failure and death if left untreated.

Current practice

Population

3.2 TAVI is primarily used in people who are at high risk for open heart surgery or when surgery is inappropriate. But it is increasingly considered as a treatment option for people who are at low or intermediate surgical risk following a position statement by NHS England, 2023. This is because eligibility is not purely based on surgical risk. In response to this statement, the Society for Cardiothoracic Surgery in Great Britain and Ireland, and the Royal College of Surgeons submitted a letter stating that the policy was not clinically appropriate and could increase a person's risk if subsequent surgery was needed. A clinical expert advised that there is little long-term evidence for TAVI in people at low surgical risk.

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Choice of valve

3.3 The clinical experts advised that the decision about which type of transcatheter heart valve to use is usually made by an interventional cardiologist as part of a multidisciplinary heart team. The decision largely depends on the clinical characteristics of the person with aortic stenosis. It may also be related to the cardiologist's experience with a particular transcatheter heart valve or the range of valves that are locally available. Most NHS trusts will have access to at least 1 self-expanding and 1 balloon-expanding valve. The clinical experts explained that the anatomy of the valve being replaced and the level and distribution of calcium are particularly important and can be strong predictors of clinical outcomes (see NICE's interventional procedures guidance on transcatheter aortic valve implantation for aortic stenosis). The committee heard that more than 50% of people with aortic stenosis would not need a specific transcatheter heart valve and a wide range could be used. But it acknowledged that, in other people, a particular valve may be more appropriate.

3.4 The committee noted that the valves being assessed vary in their indications (see section 2). The clinical experts said that most people for whom TAVI has been selected as the appropriate treatment option are at high surgical risk and have trileaflet valve anatomy. Also, most TAVI procedures are done to replace a native aortic valve. The committee noted that all the valves in the assessment are indicated for this population. A clinical expert stated that transcatheter heart valves are sometimes used outside of their intended use when this is considered the most clinically appropriate option.

Shared decision making

3.5 The committee noted the importance of communication with people having TAVI when deciding which specific transcatheter heart valve to use. The committee acknowledged that the specific valve is typically chosen by an interventional cardiologist. There is usually not a meaningful choice to be made by the person with aortic stenosis because their treatment will not differ based on which valve they have. But a patient expert said that people having TAVI value having information about the factors influencing valve choice, so that they can better understand the reasoning. Also, sometimes, people may have a strong preference

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for one valve over another. For example, their religious or cultural beliefs may mean that they would prefer a valve that does not contain specific animal products or leaflets from a particular animal tissue. The committee also noted the value of shared decision making and patient involvement across the whole care pathway.

Clinical effectiveness

Availability of clinical evidence to address the decision question

3.6 The committee acknowledged the wealth of evidence on the clinical performance of transcatheter heart valves and the relative treatment effectiveness of TAVI compared with surgical valve replacement. But it noted that there was little comparative evidence between different transcatheter heart valves and between companies. The EAG explained that it considered the UK TAVI registry (see section 3.8) the strongest source of clinical evidence. This was because it provides recent data from the UK, allowing for the assessment of different valves while adjusting for recorded confounders. The EAG explained that the available network meta-analyses were unreliable because of differences in patient characteristics in the included studies. This could have led to a breach of the assumption of transitivity (that a person could have been randomised to any of the study arms included in the analysis). The EAG also highlighted that the network meta-analyses included valves that had been withdrawn from market or were no longer available for purchase.

3.7 The committee and companies queried why randomised controlled trial (RCT) data was not considered and noted that it could provide important information, especially about long-term outcomes. The EAG noted that the assessment report's summaries of key evidence and the first and second addenda to the report included several RCTs comparing multiple transcatheter heart valves. They also included systematic reviews with network meta-analysis (that included RCTs). But the EAG explained that many RCTs identified during the evidence review included surgical valve replacement as a comparator. Other RCTs had mixed comparator arms or included older generation valves or valves no longer available in the NHS. The EAG explained that because of the recent changes in

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the populations having TAVI and surgery in the NHS, evidence from an RCT in which surgery is a comparator may not reflect current care. The EAG also explained that several published studies compared self-expandable and balloon-expandable valves. But these do not address the decision problem of this assessment, because any differences in outcomes could not be attributed to a particular valve. The committee queried whether published evidence from countries other than the UK was generalisable to the NHS. An expert adviser said that international evidence is broadly generalisable to the NHS. But a specialist committee member noted that the level of TAVI use in the UK is lower than in many other higher-income countries. They also noted that the populations may be different in terms of the proportions of people at different surgical risks. Another specialist committee member said that there are differences in standard practice for treating aortic stenosis between countries and that this can affect both resource use and clinical outcomes.

Evidence sources

3.8 The UK TAVI registry is a mandatory registry that collects information for all TAVI procedures across England, Wales and Northern Ireland. It was created to define the characteristics and clinical outcomes in people having TAVI, regardless of technology or access route, in every centre doing TAVI in the UK. The registry is managed by the National Institute for Cardiovascular Outcomes Research (NICOR) with clinical direction and strategy provided by the British Cardiovascular Interventional Society and the Society for Cardiothoracic Surgeons. The committee agreed that the dataset represented the best available evidence because it reflects clinical practice in the NHS. The committee also noted that it contains data on many relevant patient characteristics, which the EAG used to do multivariate analysis to enable comparison between valves (see section 3.11). The committee also recognised some limitations of the UK TAVI registry. It noted that linking to other datasets is necessary because the UK TAVI registry only contains data on in-hospital outcomes. The EAG was able to collate data from 7,409 procedures in which the TAVI device could be identified. But the available data only included valves from 4 companies. The clinical experts said that the UK TAVI registry was not designed to make direct valve comparisons and it does not record several clinically important patient characteristics (see section 3.3). The EAG also highlighted that many fields in the registry were poorly completed.

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3.9 To address the lack of long-term data in the UK TAVI registry, the EAG linked the data to Hospital Episode Statistics (HES) based on the NHS trust, age and sex. The EAG explained that the linked dataset censored 381 procedures from Wales and Northern Ireland and that no match was found for 520 procedures. This resulted in 6,508 matches, of which 6,270 were procedures to replace a native aortic valve. A specialist committee member queried the reliability of HES data. The EAG clarified that HES data is reliable for many routinely collected outcomes important for the cost-effectiveness analyses, such as mortality and stroke. The committee agreed that the linking was robust. But it noted that the longest follow up within the linked dataset was 31 months. So, the results could not be considered to fully represent long-term outcomes. Also, the EAG's decision to only use cases with no missing data reduced the sample size (from 6,270 to 3,917 records in the UK TAVI registry). Stakeholders highlighted this as a limitation of the real-world data analysis. They also noted that some valves were used a lot more than others.

3.10 The committee considered evidence on device-specific short- and long-term outcomes from a number of peer-reviewed studies. This included 1 network meta-analysis that included 79 studies comparing multiple valves and 6 studies comparing multiple valves while adjusting for confounders. It also included additional observational, non-randomised, single-arm and retrospective studies, summarised in the EAG's assessment report. The committee considered 2 additional studies identified as key evidence by the EAG (1 randomised trial and 1 observational, non-randomised study). These were summarised in the first addendum to the assessment report. The committee noted that the published evidence assessed by the EAG was not identified by a systematic search. The EAG acknowledged that this approach can lead to bias, but explained that this allowed it to capture the published evidence most relevant to the scope. The EAG noted that the review of published evidence intended to address gaps in the real-world evidence for valves that did not have data captured in the registry. The committee recalled that the clinical evidence review included evidence identified by the EAG, from company submissions and from stakeholder responses to public consultations. After the resolution process (see sections 3.29 to 3.32), the EAG did a systematic search for published studies comparing the clinical effectiveness of all transcatheter heart valves included in this assessment. This resulted in 5 systematic reviews and 5 primary evidence studies. These were summarised in a second addendum to the assessment report. The EAG highlighted that many of

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the studies included in the systematic reviews overlapped and were also included in other systematic reviews previously presented to the committee. It also highlighted that all of the primary evidence studies newly identified by the search were published after the original searches for the assessment report were done. The committee recognised that no key evidence had been missed when the original evidence reviews were done. The committee noted that clinically relevant confounding factors that were not captured in the UK TAVI registry were also not adjusted for in the key published evidence. It also noted that RCTs often have other limitations, including:

- eligibility criteria that do not represent clinical practice
- poor generalisability because of mixed valve types in trial arms
- a risk of publication bias, with favourable findings more likely to be reported in industry-funded trials.

The committee concluded that the UK TAVI registry was the most appropriate source of evidence, but that it could not fully answer the decision question.

Results of UK TAVI registry analyses

3.11 The committee concluded that the UK TAVI registry data did not capture all the detail needed to provide reliable estimates of relative efficacy between valves. The EAG did a multivariate analysis of the linked dataset using the patient characteristics that were available in the registry. This analysis showed statistically significant differences in the odds of having an in-hospital stroke, in-hospital aortic regurgitation and in-hospital permanent pacemaker implantation between some of the transcatheter heart valves. But there were no differences seen in outcomes after discharge from hospital. The committee noted that the analysis of the linked dataset was limited because it was not possible to adjust for some clinically important patient characteristics that are not recorded in the UK TAVI registry or HES (see section 3.3 and section 3.8). So, it was not possible to conclude whether the observed outcomes in the analyses were because of features of the valves or the clinical characteristics of the people with aortic stenosis. The EAG explained that the results were also confounded by how much a valve had been used in the NHS during the study period. This led to higher

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uncertainty for those valves that had been used less frequently. A specialist committee member explained that the most commonly used valves may be more likely to be used for people who can have a transcatheter heart valve from any company, and who are less likely to experience complications. But it is also possible that cardiologists may prefer to use the transcatheter heart valve they are most familiar with for people with more complex anatomy who are more likely to experience complications. The committee acknowledged that the differences in how much each valve is used in the NHS can have a significant impact on the certainty of the results.

Evidence for valves not captured in the UK TAVI registry

3.12 Five transcatheter heart valves (Allegra, Evolut FX, Hydra, Myval Octacor and Trilogy) had no data in the UK TAVI registry. This was because they were new to the NHS Supply Chain framework at the time of assessment. The committee noted that the published evidence identified by the EAG presented the best available evidence for these valves. But it acknowledged that this evidence was sparse, subject to bias and limitations, and only observed outcomes up to 1 year of follow up. Stakeholders expressed concerns related to using transcatheter heart valves without long-term evidence. But NHS representatives explained that transcatheter heart valves are CE-marked as class 3 implantable devices, so companies are required to submit evidence of acceptable performance and safety before their valve is added to the NHS Supply Chain framework. They also explained that the NHS Supply Chain uses a phased introduction of first-generation technologies when appropriate. The committee concluded that the valves available on the NHS Supply Chain have enough evidence to be used in the NHS. But it also concluded that the available evidence does not allow for direct comparison between different valves.

Clinical equivalence

3.13 It was not clear in the clinical evidence whether there were differences in clinical effectiveness between different companies' transcatheter heart valves that could be attributed to their innovative features. But the committee acknowledged that clinical equivalence between companies' valves could not be assumed. The

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committee recalled that, for most people with aortic stenosis, many of the available valves could be considered clinically appropriate (see section 3.3).

Relative performance between valve generations

3.14 The committee queried whether it was appropriate to assume clinical equivalence between generations of a valve from the same company. The clinical experts commented that it was inappropriate to present results of the registry analysis separately for different generations of valves from the same company, because they considered these largely equivalent. A specialist committee member and company representatives explained that newer generations usually have incremental improvements. They added that these are often small changes that may not affect certain outcomes, such as durability. The EAG highlighted that clinical studies between generations typically have short follow up and do not provide long-term data, with the longest follow up being 1 year. It stated that, because differences in clinical outcomes between generations have been seen in the literature, long-term equivalence could not be assumed. A specialist committee member said that it should not be assumed that a newer valve is non-inferior if the differences between valves are substantial (for example, changes in the leaflet tissue). This was based on the committee member's experience with surgical heart valves. The committee concluded that it was likely that newer generations of valves work as well as previous generations, but that this cannot be assumed.

Value of long-term follow up

3.15 Stakeholders commented that some families of transcatheter heart valves have been available for a long time, so follow up of people with early versions of these valves is available for up to 12 years. The committee considered evidence identified by the EAG on the longest available follow up for each valve family. The committee recalled that older data can be less relevant because of differences in the population, clinical pathway and transcatheter heart valves themselves (see section 3.7). The clinical experts noted that the UK TAVI registry will need ongoing support to capture long-term follow-up data.

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Economic evaluation

Economic model structure

3.16 The EAG adapted the economic model used in the economic evaluation of TAVI for NICE's guideline on heart valve disease presenting in adults: investigation and management (from here NG208) to allow for direct comparisons of different transcatheter heart valves. The committee considered the structure and assumptions of the EAG's economic model. It agreed that it was an appropriate representation of clinical practice in the NHS.

Model clinical inputs

3.17 The committee concluded that the clinical inputs to the economic model had limitations, because they relied on the results of the multivariate analysis of the UK TAVI registry, which were highly uncertain (see section 3.11). The transition probabilities between health states in the model were calculated from the event rates in the linked dataset. The committee recalled the bias and limitations associated with this dataset, which it agreed led to significant bias in the results of the economic model.

3.18 Expert advisers and the companies suggested that data from RCTs could be used to inform the economic model, especially for long-term outcomes. The EAG explained that using data from different sources for different outcomes is likely to give biased results because they will not account for all clinically important characteristics. The committee recalled the limitations of the RCTs that would affect their ability to inform clinical parameters in the model. These included having:

- surgery as a comparator
- older generation valves or valves no longer available in the NHS in the trial arms
- an inappropriate design (for example, mixed device arms or trials comparing self-expandable and balloon-expandable valves as broad groups without

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specifying the exact device; see section 3.7).

The EAG said that correcting for these factors would be challenging and would introduce further uncertainty. It highlighted that simultaneously sourcing all clinical inputs was a significant methodological advantage of using the UK TAVI registry data. It also noted that using different sources for clinical inputs was cited by stakeholders as a limitation of the economic evaluation in NG208. The committee agreed that using results from the multivariate analysis of the UK TAVI registry for clinical inputs in the economic model was more appropriate.

Model cost inputs

3.19 Some companies have 'added value' agreements with the NHS Supply Chain, in which part of the cost of the valve is returned based on the number of valves purchased. The committee concluded that it was appropriate to account for these 'added value' agreements in the valve cost. But it acknowledged that changes in the volume of use could affect the actual price of some valves. It highlighted that the price variation between the valves after the 'added value' was accounted for was smaller than the variation at list prices, but that price variation still remained. It also noted that, often, the resources returned through 'added value' agreements can only be spent on structural heart-related products or services at the NHS trust level. Industry representatives said that the money returned through 'added value' agreements would be spent on products and services that would be needed with or without the agreements. Another stakeholder said that 'added value' agreements are anticompetitive and discourage uptake of newer valves.

Cost effectiveness of different transcatheter heart valves

3.20 The committee concluded that the model results were too uncertain to determine whether there were differences in the cost effectiveness of the transcatheter heart valves. The EAG presented the results of the economic evaluation in terms of net monetary benefit including the central value and the 95% confidence

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interval. The committee noted that, although there were differences in the net monetary benefit of the different valves, the confidence intervals overlapped significantly. The committee agreed that it was not possible to establish whether the differences in net monetary benefit were because of differences in valve performance, or confounding in the clinical data used to inform parameters in the economic model (see section 3.11).

Resource impact

3.21 The committee considered a hypothetical scenario that modelled a conservative estimate showing the financial impact of shifting towards less expensive valves without considering potential clinical differences. The committee concluded that switching to less expensive valves (even considering 'added value' agreements) could result in net cost savings for the system. A specialist committee member said that their NHS trust gets significant resources through 'added value' agreements, which would have to be funded through other means if different valves are used.

Justification for price variation

3.22 The committee concluded that it was not possible to determine whether the differences in cost between valves were justified by benefits derived from incremental innovations. The committee considered the combined clinical and economic evidence and recalled its limitations (see sections 3.6 to 3.12, section 3.20 and sections 3.31 and 3.32). It was unable to establish which valve features lead to differences in performance and recalled that the specific transcatheter heart valve chosen often depends on the characteristics of the person with aortic stenosis (see section 3.3). It recalled that clinical equivalence could not be assumed between transcatheter heart valves from different companies or between generations of transcatheter heart valves by the same company. But it is likely that, for many people, any valve could be considered clinically appropriate (see sections 3.13 and 3.14). The committee emphasised the importance of having access to a range of valves, so that a clinically appropriate valve is always available.

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3.23 The committee concluded that the availability of long-term data for a valve family does not justify a higher price for current iterations. It recalled that healthcare professionals and people with aortic stenosis value the availability of long-term data. But long-term data is often less relevant because of differences in the population, clinical pathway and the transcatheter heart valves themselves (see section 3.15). The committee also recalled that NHS England has established mechanisms to ensure that all valves on the NHS Supply Chain framework have shown acceptable performance and short-term safety outcomes for at least 1 year (see section 3.12).

User preference assessment

3.24 The committee concluded that most of the reasoning for choosing a specific valve is based on clinical factors and outcomes, so price differences could not be justified by other non-clinical factors. It considered evidence from a user preference assessment that sought to specifically establish which features of a TAVI valve influence a user's decision about which valve to choose. It noted that, of the 7 most important criteria identified, 5 (including the top 3) were captured in the EAG's assessment. They accounted for 87% of the weight of users' decision making. The remaining factors were either not possible to account for because they related to characteristics not captured in the clinical data (see section 3.8), or technical features that made up only 6% of the overall preference. Stakeholders noted that the sample of users varied throughout the user preference assessment, but was generally small.

Evidence needed to show additional value

3.25 The committee concluded that more evidence is needed for companies to show the additional value of a transcatheter heart valve compared with its alternatives. This evidence should be comparative and should adjust for clinically relevant patient characteristics, including the anatomy of the valve being replaced, the impact of calcium around the valve and the person's age, sex, ethnicity and medical history. The committee heard that surgical risk does not generally affect the decision about which valve to use, only whether to do TAVI or open heart surgery. But it recalled that some valves are not indicated for all surgical risk

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groups. So, the committee thought that collecting data on surgical risk to investigate potential confounding by indication was important. It also said that, if a company claims to have a valve with incremental innovations, it should be able to show clinical superiority to justify a higher price for the valve. Also, if a company is introducing a new valve or a new generation of the technology with minor improvements to the market, it should show clinical non-inferiority. The committee acknowledged that the lack of evidence of additional value of a transcatheter heart valve compared with its alternatives in the evidence review does not mean that a difference does not exist.

3.26 The committee discussed whether further data collection in the UK TAVI registry could be used to address the uncertainties in the current analyses. The clinical experts explained that this would need additional clinically relevant patient characteristics to be recorded in the registry. They also said that some characteristics, such as the level of calcium in and around the valve, can be challenging to capture. The experts added that collecting information on healthcare professional time and length of stay in intensive care or high dependency units could help improve the accuracy of cost estimates. The clinical lead for the UK TAVI registry at NICOR explained that the registry is working with NHS England and commissioned hospitals to improve data collection. It is also engaged with the Medical Device Outcome Registry to facilitate the generation of information about device-specific long-term outcomes. The clinical experts also advised that the UK TAVI registry is limited to in-hospital outcomes and that missing data for some fields is prevalent. They said that additional administrative support and funding would be needed to ensure high-quality registry data collection. It is mandatory to record all TAVI procedures in England, Wales and Northern Ireland in the UK TAVI registry. The EAG explained that because of this the UK TAVI registry could eventually provide evidence for the long-term clinical effectiveness of the transcatheter heart valves used currently, if TAVI procedures are linked to long-term outcomes data from other sources.

Equality considerations

3.27 The committee concluded that a range of transcatheter heart valves should be available so that equality issues are not introduced. All valves contain bovine or porcine leaflets, so some people may not accept specific valves because of their

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religious or cultural beliefs. Transcatheter heart valves are available in different size ranges and design features, which may affect whether they can be used in people with different anatomical features. For example, women are more likely to have a smaller aortic annulus and need a smaller valve, or a valve with a particular feature, to ensure better outcomes. Having access to a range of valves will ensure that a clinically appropriate valve that is acceptable to the person with aortic stenosis is available (see section 3.5). Shared decision making will ensure that a person's preference is considered (see what this means in practice).

3.28 The committee heard that there are inequalities in access to TAVI related to ethnicity and socioeconomic status. The committee concluded that guidance on the choice of valve would not affect access to care because the decision is made after TAVI has been established as a possible treatment option.

Considerations after resolution

3.29 Resolution requests were referred to a resolution panel under the claim that there was a breach of NICE's published process, as outlined in section 7.2 on resolution for interventional procedures and HealthTech guidance in NICE's health technology evaluations manual.

3.30 The draft guidance shared for resolution recommended that healthcare professionals should choose the most cost-effective valve if more than 1 is clinically appropriate. The economic analyses done for NG208 comparing TAVI with surgery were cited to provide a reference for a cost-effective price for a valve. The panel decided that referencing NG208 represented a potential breach of process. So, it recommended that the committee reconsider the relevance of using NG208 to cross-reference cost-effectiveness thresholds and to determine value for money. The panel decided that there was no breach of process because of the processes and methods used. But it advised that the EAG's approach to evidence searching and selection should be reviewed by the committee.

3.31 The committee considered a report by NICE's surveillance team that suggested that evidence which has become available since the publication of NG208 could potentially change the results of the economic modelling done for the guideline. The clinical experts added that there have been changes in the care pathway and

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in the characteristics of people who have surgical valve replacement or TAVI. So, the committee concluded that it was uncertain whether the price thresholds for cost-effectiveness of TAVI against surgery reported in the economic analysis for NG208 were relevant to these recommendations. The committee agreed that it was outside the remit of this late-stage assessment to assess the cost effectiveness of TAVI compared with surgical valve replacement. So, it said that reference to the price thresholds for cost effectiveness of TAVI against surgery reported in NG208 should be removed from this late-stage assessment.

3.32 The committee agreed that the EAG's original approach to evidence searching and selection was reasonable and appropriate. It considered the additional evidence from the systematic review for published literature comparing the clinical effectiveness of all transcatheter heart valves (see section 3.10). The clinical experts noted that the field is rapidly developing, and none of the new evidence identified was published at the time of the EAG's original searches. The EAG said that its conclusions about the relative clinical effectiveness of the valves in scope were not changed by the new evidence. The EAG also reiterated the issues with using randomised evidence to inform the economic model (see section 3.18).

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4 Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Professor Tom Clutton-Brock
Chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the evaluation), a technical adviser, a project manager and an associate director.

Ivan Maslyankov
Technical lead

Jacob Grant
Technical adviser

Bruce Smith
Project manager

Anastasia Chalkidou and Lizzy Latimer
Associate directors

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Update information

Minor changes since publication

December 2025: Health technology evaluation 31 has been migrated to HealthTech guidance 757. The recommendations and accompanying content remain unchanged.

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