NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTHTECH PROGRAMME

Draft guidance

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

Guidance development process

Late-stage assessment (LSA) guidance evaluates categories of technologies that are already in widespread use within the NHS. It assesses whether price variations between technologies in a category are justified by differences in innovation, clinical effectiveness and patient benefits. This will support NHS commissioners, procurement teams, patients and clinicians to choose technologies that maximise clinical effectiveness and value for money.

Find out more on the NICE webpage on late-stage assessment (LSA) for medtech.

This guidance does not replace existing guidance on when to use TAVI to treat aortic stenosis. It only provides information on which valves should be considered once the decision to do TAVI has been made, and on the evidence comparing different types of valve.

The National Institute for Health and Care Excellence (NICE) is producing guidance on using transcatheter heart valves for transcatheter aortic valve implantation to treat aortic stenosis in the NHS in England. The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the

recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the evidence (the external assessment report).

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology.
- could have any adverse effect on people with a particular disability or disabilities.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on transcatheter heart valves for transcatheter aortic valve implantation to treat aortic stenosis. The recommendations in section 1 may change after consultation.

After consultation, the committee will meet again to consider the evidence, this document and comments from the consultation. After considering the comments the committee will prepare its final recommendations. For further

details, see NICE health technology evaluations: the manual and NICE's late-stage assessment interim process and methods statement.

Key dates

Closing date for comments: 2 September 2024

Second medical technologies advisory committee meeting: 17 October 2024

1 Recommendations

1.1 There is not enough evidence to determine whether incremental innovations can justify price variations between different transcatheter heart valves for transcatheter aortic valve implantation (TAVI) in adults with aortic stenosis.

1.2 Use the least expensive option available that is clinically appropriate for TAVI in the person with aortic stenosis.

1.3 NHS trusts should provide access to a range of valves, so that the most clinically appropriate valve is available for everyone with aortic stenosis.

What information is needed

More information is needed to determine whether price variation can be justified between different transcatheter heart valves. Details of all patients should be entered into the UK TAVI registry to enable robust comparisons. Key outcomes and information that should be captured include:

- mortality
- stroke
- paravalvular leak or aortic regurgitation
- permanent pacemaker implantation
- reintervention
- the specific valve used.

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

- the anatomy of the valve being replaced
- the level and distribution of calcium around the valve
- the person's surgical risk
- the person's age, sex, comorbidities and previous medicine use.

These outcomes and baseline characteristics will also need to be recorded in the UK TAVI registry.

What this means in practice

Procurement and commissioning considerations

- Analyses from the economic evaluation done for NICE's guideline on heart valve disease presenting in adults: investigation and management indicated that a transcatheter heart valve would have to cost £14,800 or less for the procedure to be cost effective for all surgical risks. Most of the transcatheter heart valves currently available in the NHS cost more than £14,800 at their list price.
- 'Added value' agreements between companies and NHS Supply Chain allow for part of the cost of a valve to be returned to an NHS trust based on the number of valves purchased. This can typically only be spent on structural heart-related items or staff within the trust, so will not be resource-releasing for the NHS. Most of the transcatheter heart valves currently available in the NHS cost more than £14,800 even after accounting for 'added value' agreements. The NHS may benefit more from negotiating prices that would be cost-effective across all surgical risk groups than from using those with 'added value' agreements.
- The number of TAVI procedures done annually is rising (NICOR UK TAVI registry 2024 summary report).

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 aims to determine whether the differences in clinical, economic and non-clinical outcomes between the different valves attributed to innovative features or characteristics of the valves could justify price variation.

For most people with aortic stenosis, many of the available valves could be used and are likely to be clinically comparable. For some people a specific valve may be more appropriate. The effectiveness of individual valves is likely to depend both on 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. The results from an economic evaluation based on the real-world data analyses are too uncertain to determine whether the differences in cost between valves are justified.

More evidence is needed to show if differences in price between valves can be justified by differences in effectiveness. New valves should be able to show that they work as well as other valves. Evidence needs to be comparative and needs to adjust for baseline characteristics that have a large impact on outcomes. These baseline characteristics will also need to be recorded in the UK TAVI registry. This is to ensure that results reflect the performance of the valve used and not the people it is used in.

2 The technologies

2.1 Transcatheter heart valves are used for a transcatheter aortic valve implantation (TAVI) procedure, 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, the type of tissue of the leaflets and the available valve sizes. They also vary in technical characteristics such as the expansion mechanism, the presence of locators or anchors and the valve positioning relative to the native aortic valve.

2.2 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 and the minimum vessel size for access.

2.3 Eleven transcatheter heart valves were available on NHS Supply Chain and included in this assessment. All of them had valid CE certification as class III implantable devices.

ACURATE neo2 (Boston Scientific)

2.4 ACURATE neo2 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. It is indicated for relief of aortic stenosis in people with symptomatic heart disease due to severe native calcific aortic stenosis when a heart team, including a cardiac surgeon, decides that a transcatheter heart valve replacement is appropriate.

Allegra (Biosensors)

2.5 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

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

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

2.6 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 adults presenting with severe native aortic valve stenosis. In severe native bicuspid aortic valve stenosis, the Evolut transcatheter heart valves are indicated for people at intermediate or greater risk for surgical aortic valve replacement (SAVR), or 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 systems are indicated for people aged 70 and older with a left ventricular ejection fraction (LVEF) above 30%. Evolut R, Evolut Pro+ and Evolut FX are also indicated for people with a stenosed, insufficient, or combined surgical bioprosthetic valve failure needing valve replacement who are at high or greater risk for SAVR, or there is a documented heart team agreement of risk for SAVR because of frailty or comorbidities. High risk is defined as STS operative risk score of 8% and above. 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 has an updated delivery system.

Hydra (SMT)

2.7 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 people with severe degenerative aortic stenosis presenting with a high predictable operative mortality risk for surgical aortic valve replacement. The decision is based on the clinical judgment of the heart team.

Myval Octacor (Meril)

2.8 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 relief of 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 (STS operative risk score of 4% and above risk of mortality at 30 days).

Navitor (Abbott)

2.9 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. Navitor is indicated for people with symptomatic severe native aortic stenosis who are considered high or extreme risk for SAVR.

Sapien 3 and Sapien 3 Ultra (Edwards)

2.10 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 people with severe, symptomatic, calcific aortic valve stenosis who a heart team considers to be at intermediate or greater risk for open heart surgery. Intermediate or greater risk is defined as a predicted risk of surgical mortality of 3% and above at 30 days, based on the STS risk score and other clinical comorbidities unmeasured by the STS risk calculator. The valves are also indicated for people with symptomatic heart disease due to failure (stenosed, insufficient, or combined) of a surgical bioprosthetic aortic valve or a surgical bioprosthetic mitral valve who a heart team, including a cardiac surgeon, considers to be at high or greater risk for open surgical therapy. 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)

2.11 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 people with native symptomatic, severe aortic regurgitation or symptomatic, severe aortic stenosis who a heart team, including a cardiac surgeon, considers 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.

3 Committee discussion

The advisory committee considered evidence on 11 transcatheter heart valves for transcatheter aortic valve implantation (TAVI) in people with aortic stenosis from several sources to determine whether price variation between the valves could be justified by differences in their clinical, cost effectiveness or non-clinical outcomes important to users. These included clinical evidence from analyses of real-world UK data by the external assessment group (EAG), a targeted review of the published literature, evidence submitted by the companies and responses from stakeholders. The committee also considered the economic evidence from a review of the published literature, an economic evaluation done by the EAG and a user preference assessment done by NICE.

The condition

3.1 Aortic stenosis occurs when the aortic valve thickens or stiffens and does not open properly. The prevalence among people aged over 55 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 heart surgery or for whom 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. In response to this statement, the Society for Cardiothoracic Surgery in Great Britain & Ireland and the Royal College of Surgeons submitted a letter stating that the policy was not clinically appropriate and could increase patient risks if subsequent surgery was needed.

Choice of valve

3.3 Clinical experts advised that the decision about which type of transcatheter heart valve to use is usually made by an interventional cardiologist and largely depends on the clinical characteristics of the person with aortic stenosis. The decision may also be related to the clinician'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, the level and distribution of calcium and the person's surgical risk are particularly important and can be strong predictors of clinical outcomes. The committee heard that most people with aortic stenosis (that is, more than 50%) would not need a specific transcatheter heart valve and a wide range could be used.

3.4 The committee noted that the valves being assessed vary in their indications (see section 2). Clinical experts stated that most people having TAVI are at high surgical risk, with a tricuspid 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 indication when this is considered clinically appropriate.

Shared decision making

3.5 The committee noted the importance of communication with patients when making decisions about which specific transcatheter heart valve has been chosen. The committee acknowledged that the specific valve is typically chosen by an interventional cardiologist and that 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 stated that people having TAVI value having information about the

factors influencing valve choice, so that they can better understand the reasoning. 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 surgery. 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 is because it provided recent data from the UK, and allowed the assessment of multiple valves, while adjusting for recorded confounders. The EAG explained that 4 available network meta-analyses were unreliable because of differences in patient characteristics in the included studies. This can lead to a breach of the assumption of transitivity (that a patient 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 1 non-inferiority RCT comparing multiple transcatheter heart valves and 4 network meta-analyses (that included RCTs) were included in the evidence summary. But it explained that most RCTs identified during the evidence review included surgery as a comparator, and often included older generation valves or valves no longer available in the NHS. The

EAG explained that because of the recent changes in the populations having TAVI and surgery in the NHS, evidence from an RCT where surgery is a comparator may not reflect current care. 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 and that the populations may be different in terms of the proportions of people at different surgical risks.

Quality of UK TAVI registry data

3.8 The UK TAVI registry is a mandatory registry that collects information for all TAVI procedures across England, Wales and Northern Ireland. The UK TAVI registry 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 with clinical direction and strategy provided by the British Cardiovascular Interventional Society and the Society for Cardiothoracic Surgeons. The committee agreed that the dataset reflects clinical practice in the NHS, but that it has limitations. The EAG was able to collate data from 7,409 procedures where the TAVI device could be identified. It explained that the registry only contains data on in-hospital outcomes and that the available data only included valves from 4 companies. Clinical experts stated that several clinically important patient characteristics (see section 3.3) are not recorded in the UK TAVI registry, and that it was not designed to make direct valve comparisons. The EAG also highlighted that many fields in the registry were poorly completed.

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. The committee agreed that the linkage 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 markedly reduced the sample size (to 3,917 from 6,270 records in the UK TAVI registry).

Results of UK TAVI registry analyses

3.10 The committee concluded that the UK TAVI registry data did not capture enough detail to provide reliable estimates of relative efficacy between valves. Multivariate analysis of the linked dataset showed statistically significant differences in the odds of experiencing in-hospital stroke, in-hospital aortic regurgitation and in-hospital permanent pacemaker implantation between some of the transcatheter heart valves. These differences were not 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 clinically important patient characteristics that are not recorded in the UK TAVI registry or HES (see section 3.3). 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 are also confounded by how much a valve has been used in the NHS during the study period. This leads to higher uncertainty for those valves that have 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 validity of the results.

Published evidence

3.11 The committee considered evidence on device-specific short and long-term outcomes from a number of peer-reviewed studies identified by the EAG. This included 4 network meta-analyses comparing multiple valves, 4 studies comparing multiple valves while adjusting for confounders, as well as a number of additional observational, non-randomised, single-arm and retrospective studies. 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 was a pragmatic choice given the abundance of published evidence, intended to address gaps in the real-world evidence.

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 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 it was sparse and subject to bias and limitations.

Clinical comparability between companies

3.13 It was not clear in the clinical evidence whether there are differences in clinical effectiveness between different companies' transcatheter heart valves due to incremental innovations between the valves. But, the committee acknowledged that clinical

equivalence between companies' valves could not be assumed. The committee recalled that for most people with aortic stenosis, many of the available valves could be used (see section 3.3). So, it is likely that for those people the valves are clinically comparable.

Relative performance between valve generations

3.14 The committee queried whether it is appropriate to assume clinical equivalence between generations of a valve from the same company. 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 usually newer generations make incremental improvements and that these are often small changes which would not affect 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, since differences in clinical outcomes between generations have been seen in the literature, long-term equivalence could not be assumed. A specialist committee member stated 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 is likely that newer generations of valves work as well as previous generations, but that this cannot be assumed.

Economic evaluation

Economic model structure

3.15 The EAG adapted the economic model used in the economic evaluation for NICE's guideline on heart valve disease presenting in adults: investigation and management (from now, NG208), to

allow for direct comparisons of different transcatheter heart valves. The committee considered the structure and assumptions of the EAG's economic model and agreed that it was an appropriate representation of clinical practice in the NHS.

Model clinical inputs

3.16 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 3.10). 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 and agreed that this leads to significant bias in the results of the economic model.

3.17 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 EAG also noted that although longer-term data is available from RCTs, it is restricted to comparisons of older generation valves, often with surgery as a comparator. The EAG 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.

Model cost inputs

3.18 Some companies have 'added value' arrangements with NHS Supply Chain, in which part of the cost of the valve is returned to be spent on related items or staff, based on the number of valves purchased. The committee concluded that it was appropriate to

account for these ‘added value’ arrangements in the valve cost, but acknowledged that changes in the volume of use could affect the effective 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 between the list prices. It also noted that the resources returned through ‘added value’ agreements can only be spent on structural heart-related products or services at the NHS trust level. The committee heard that analyses from the economic evaluation done for NG208 indicated that a transcatheter heart valve would have to cost £14,800 or less for the procedure to be cost effective for all surgical risks. Most of the transcatheter heart valves currently available in the NHS are above this price at both their list price and after ‘added value’ agreements have been accounted for.

Cost effectiveness

3.19 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 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 is not possible to establish whether the differences in net monetary benefit were because of differences in valve performance or because of confounding in the clinical data used to inform parameters in the economic model (see section 3.10).

Resource impact

3.20 The committee considered a hypothetical scenario that modelled a conservative estimate of a 10% market shift towards less expensive valves without considering potential clinical differences. It concluded that switching to less expensive valves priced below

the cost-effectiveness threshold that covers all surgical risk groups (see section 3.18) could result in a cost saving for the NHS, which could fund additional TAVI procedures if reinvested into the service.

Justification for price variation

3.21 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 3.16, 3.19 and 3.20). 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 that it was likely that they were clinically comparable (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.

3.22 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 establish specifically 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

were technical features that made up only 6% of the overall preference.

Evidence needed to demonstrate additional value

3.23 The committee concluded that more evidence was needed for companies to demonstrate 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. The committee stated that companies should be able to show clinical superiority to justify a higher price for their valve if it claims to have incremental innovations, or clinical non-inferiority if they are introducing a new valve or a new generation of the technology with minor improvements to the market.

3.24 The committee discussed whether further data collection in the UK TAVI registry could be used to address the uncertainties in the current analyses. Clinical experts explained that this would need additional clinically relevant patient characteristics to be recorded in the registry. The clinical experts also noted that the UK TAVI registry is limited to in-hospital outcomes and that missing data for some fields is prevalent. They stated that additional administrative support would be needed to ensure high-quality registry data collection.

Equality considerations

3.25 The committee concluded that a range of transcatheter heart valves should be available to a clinician to avoid introducing equality issues. Some people may not accept or may have preferences for specific valves because of religious or cultural beliefs, because they contain bovine or porcine leaflets. Transcatheter heart valves are available in different size ranges, which may affect whether they can be used in people with different body sizes (for example, men are more likely to have a large aortic annulus and need a larger valve). Having access to a range of

valves will ensure that a clinically appropriate valve is available that is acceptable to the person with aortic stenosis (see section 3.5).

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.

NICE also recruited clinical experts and specialist committee members for this topic.

Specialist committee members

Betsy Evans

Consultant cardiac surgeon, Leeds Teaching Hospitals NHS Foundation Trust

Charles Spencer

Advanced clinical practitioner, South Warwickshire University NHS Foundation Trust

Clare Appleby

Consultant interventional cardiologist, Liverpool Heart and Chest Hospital NHS Foundation Trust

Jon Anderson

Consultant cardiac surgeon, Imperial College Healthcare NHS Trust

Marjan Jahangiri

Consultant cardiac surgeon, St George’s University Hospitals NHS Foundation Trust

Muhammad Aetesam-ur-Rahman

Consultant interventional cardiologist, Sheffield Teaching Hospitals NHS Trust

Richard Jabbour

Consultant interventional cardiologist, University Hospital Southampton NHS Foundation Trust

Suvitesh Luthra

Consultant cardiac and aortic surgeon, University Hospitals Southampton NHS Foundation Trust

Clinical experts

Dan Blackman

Consultant cardiologist, Leeds Teaching Hospitals NHS Trust

David Hildick-Smith

Consultant cardiologist, University Hospitals Sussex NHS Foundation Trust; President of the British Cardiovascular Intervention Society