

HealthTech Programme

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

Equality impact assessment: Guidance

Final draft guidance

1. Have the potential equality issues identified during the scoping process been addressed by the committee, and, if so, how?

The committee considered the equality issues identified during the scoping process related to TAVI as a procedure. It noted that cultural preferences and religious beliefs may influence the acceptability of some devices in certain societal groups, related to the use of bovine and porcine tissue for the leaflets of transcatheter heart valves. It noted that recommendation 1.2 states that “NHS trusts should provide access to a range of valves, so that the most clinically appropriate valve is available for everyone with aortic stenosis having TAVI”. The committee noted that maintaining choice would result in the availability of an acceptable device for all societal groups. It also noted that shared decision making will ensure that the preferences of the person having TAVI are taken into account.

The committee also considered the equality considerations identified during the scoping process related to aortic stenosis. It noted that the prevalence of aortic stenosis rises with age. It also noted that there are geographical inequalities with regards to access to heart valve clinics and that there may be gender inequalities in terms of lower treatment rates in females. The committee judged that access to treatment would not be affected by the recommendations in the guidance, as these factors are not related to the choice of specific device.

2. Have any other potential equality issues been raised in the external assessment report, and, if so, how has the committee addressed these?

The external assessment group highlighted that all devices included in the assessment contain nickel and that the prevalence of an allergy or hypersensitivity to nickel is higher in females. The external assessment

group summarised all evidence on nickel-related adverse events provided by the companies. The committee considered this evidence. It also heard that screening for nickel allergy is not routinely done, nor does it influence the choice between transcatheter heart valves. It judged that access to treatment would not be affected by this equality issue.

3. Have any other potential equality issues been identified by the committee, and, if so, how has the committee addressed these?

The committee noted that transcatheter heart valves are available in different size ranges and design features, which may affect whether they can be used in people with different body sizes. This can potentially affect inequalities related to access, because women are more likely to have a smaller aortic annulus and so, more likely to need a smaller valve or a valve with a particular feature. The committee concluded that having access to a range of valves will ensure that a clinically appropriate valve is available for the person with aortic stenosis.

The committee considered potential inequalities related to ethnicity. It heard that there may be inequalities in access to TAVI related to ethnicity, but that this is also highly affected by socioeconomic and geographical inequalities (see question 1). The committee concluded that the recommendations would not affect access to treatment for aortic stenosis, because the decision is made after TAVI has been established as a possible treatment option, so they will not have an adverse impact on people from disadvantaged groups. But, the committee concluded that ethnicity should be collected and adjusted for in future research (see What information is needed).

4. Do the recommendations make it more difficult in practice for a specific group to access the technology compared with other groups? If so, what are the barriers to, or difficulties with, access for the specific group?

The recommendations would not affect access to treatment for aortic stenosis.

5. Is there potential for the recommendations to have an adverse impact on people with disabilities because of something that is a consequence of the disability?

No.

6. Are there any recommendations or explanations that the committee could make to remove or alleviate barriers to, or difficulties with, access identified in questions 4 or 5, or otherwise fulfil NICE's obligations to promote equality?

See answer to question 4.

7. Have the committee's considerations of equality issues been described in the guidance document, and, if so, where?

Equality issues and considerations have been described in sections 3.27 and 3.28 of the guidance.

Approved by Associate Director: Lizzy Latimer

Date: 13 August 2025