NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1980 Transcatheter aortic valve implantation for aortic incompetence**

Your information

Name:	Dr Mohamed Elamin
Job title:	Consultant Interventional Cardiologist
Organisation:	1. Royal Derby Hospital. 2. Glenfield Hospital, Leicester
Email address:	[redacted]
Professional organisation or society membership/affiliation:	JRCPTB, BCIS
Nominated/ratified by (if applicable):	Dr Damian Kelly
Registration number (e.g. GMC, NMC, HCPC)	7062497

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☒ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am a TAVI operator at Glenfield Hospital, Leicester. I am very familiar with the procedure and devices related to aortic stenosis. However, the use of TAVI in Pure non-calcified aortic regurgitation remains challenging due to lack of calcification which provides anchoring of the valve prosthesis. We have performed a few highly selected pure AR cases with self-expanding platforms with good results despite the technical difficulties. However, this remains 'off-lable'. I have not used dedicated pure AR devices such as JenaValve or J-valve.
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	-The number of TAVI centres in the NHS is one of the lowest per million population (0.53) compared to other European countries. There are over 500 avoidable deaths annually because of the long waiting times. The uptake is very slow due to restrictions in expanding the procedure to non-surgical centres, and the oversaturated capacity in surgical centres.
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	-Not in my centre. However, I'm aware that in some centres Cardiac surgeons also do the procedure.
	– If your specialty is involved in patient selection or referral to another specialty for this	- We have established a TAVI clinic at the Royal Derby hospital (non-TAVI centre), where patients can be assessed and counselled locally. This has significantly reduced the length of time from diagnosis to procedure, and improved patient experience.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. I have had no involvement in research on this procedure. Other (please comment): We are currently writing up an article regarding the effect of establishing a TAVI clinic at the Royal Derby hospital on the wating times.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	I suggest: Transcatheter Aortic valve implantation for pure non-calcified aortic incompetence The technology using the standard devices for aortic stenosis is well established. However, implantation of the same devices in pure aortic regurgitation is technically difficult and unpredictable due to lack of anchoring. There are dedicated devices for aortic regurgitation, however they are not widely used. Established practice and no longer new. A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy. (**X**) Definitely novel and of uncertain safety and efficacy.

		The first in a new class of procedure.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	The standard of care is surgical aortic valve replacement, however, there are growing numbers of small case series that show safety and efficacy of using the devices for pure aortic regurgitation.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	There are 2 dedicated devices for pure AR, however they are not widely used. The standard devices has also been used with some success in selected cases. This requires careful patient and device selection. There are small case series that show success. There are no published large randomised trials.

Current management

6	Please describe the current standard of care that is used in the NHS.	The current standard of care is surgical aortic valve replacement. Some selected cases are accepted through the Heart team meeting.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Improves outcomes, and reduce admissions with decompensated heart failure.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients who are not suitable for surgical aortic valve replacement but deemed suitable for TAVI with good chance of success by the Heart team.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes. When done successfully it improves outcomes and reduce hospital admissions.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The main challenge is the small number of TAVI centres in the UK, which are mainly treating Aortic stenosis and failed tissue AVR. This can be improved by expanding the procedure into non-surgical centre in selected cases, in order to improve the capacity in surgical centres to treat more complex cases such as pure aortic regurgitation.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	All the potential complications associated with TAVI for aortic stenosis, in addition to high risk of valve embolization, and higher incidents of paravalvular leak which leads to worse clinical outcomes. There is a long history of 'off-label' TAVI for pure AR. One of the well-known papers that looked into the outcomes is Yoon S, Schmidt T, Bleiziffer S, et al. Transcatheter Aortic Valve

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Replacement in Pure Native Aortic Valve Regurgitation. J Am Coll Cardiol. 2017 Dec, 70 (22) 2752–2763. https://doi.org/10.1016/j.jacc.2017.10.006 Another recently published paper using dedicated devices is: Pierluigi Costanzo, Paul Bamborough, Mark Peterson, Djeven J Deva, Geraldine Ong, Neil Fam, Transcatheter Aortic Valve Implantation for Severe Pure Aortic Regurgitation With Dedicated Devices, *Interventional Cardiology 2022;17:e11.* https://doi.org/10.15420/icr.2021.19 The main adverse events from experience are embolization of the valve and moderate/severe paravalvular leak.
14	Please list the key efficacy outcomes for this procedure/technology?	The mortality of symptomatic severe AR is about 9.4% per year. This is more in patients with NYHA III/IV to around 24.6%. The procedural outcomes are widely different depending on patient and device selection. From observational data, the all-cause 30 day mortality is about 10%.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Patient selection. Device selection.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. (**X**) Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Pierluigi Costanzo, Paul Bamborough, Mark Peterson, Djeven J Deva, Geraldine Ong, Neil Fam, Transcatheter Aortic Valve Implantation for Severe Pure Aortic Regurgitation With Dedicated Devices, *Interventional Cardiology 2022;17:e11.* https://doi.org/10.15420/icr.2021.19 Yoon S, Schmidt T, Bleiziffer S, et al. Transcatheter Aortic Valve Replacement in Pure Native Aortic Valve Regurgitation. J Am Coll Cardiol. 2017 Dec, 70 (22) 2752–2763. https://doi.org/10.1016/j.jacc.2017.10.006
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	
20	Please list any other data (published and/or unpublished) that you would like to share.	De Backer O, Pilgrim T, Simonato M et al. Usefulness of transcatheter aortic valve implantation for treatment of pure native aortic valve regurgitation. *Am J Cardiol.* 2018;122:1028–35. doi: 10.1016/j.amjcard.2018.05.044. Kumar A, Sato K, Banerjee K Hemodynamic durability of transcatheter aortic valves using the updated Valve Academic Research Consortium-2 criteria. *Catheter Cardiovasc Interv.* 2018

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	Around 2% of elderly population has moderate/severe aortic regurgitation which can be considered for the procedure.

22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: – Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Device success. Improvement in LV ejection fraction and regression of LV hypertrophy. Improvement of NYHA class and reduction in unplanned hospital admissions. Adverse outcome measures: All-cause mortality (30-day and 1 year) CV mortality Second valve implantation AR/PVL > moderate

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Large-scale randomised trials are needed

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Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	No declarations		
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Mohamed Elamin**
Dated:	**22/07/2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1980 Transcatheter aortic valve implantation for aortic incompetence**

Your information

Name:	Andreas Baumbach
Job title:	Professor of Cardiology
Organisation:	Barts Heart Centre
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BCIS, BCS, ESC, EAPCI
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4674919

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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x☐ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Very familiar with the technology. We were the first centre in the UK to use the valve and have developed a clinical programme and research study on patients with pure aortic regurgitation.
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	We have done 20 procedues at Barts. Leeds have now started with 6+ and Oxford. This is for patients that cannot be operated on. The selection is via MDT meeting, similar to aortic stenosis and TAVI

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. I lead on educational events (Session at PCR London valves in November) for this topic
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes The indication is Symptomatic severe aortic regurgitation in patients not suitable for surgical aortic valve replacement The first valve dedicated (and CE marked) to aortic regurgitation and aortic valve disease without calcification.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Expansion of standard of care. Currently the use of standard TAVI valves is associated with increased risk of embolization and paravalvulare leaks, as well as need for second valves. Increased mortality has been reported.

5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	New Trilogy system (Jenavalve) is the first dedicated system for aortic valve conditions without valve calcification.

Current management

6	Please describe the current standard of care that is used in the NHS.	Surgical aortic valve replacement. For inoperable patients, use of TAVI with non-dedicated devices is common.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	no

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Immediate symptomatic benefit
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Once established, a larger cohort of elderly patients with AR can be treated with TAVI rather than surgery
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes, improved outcomes, earlier trestment of AR
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Cathlab, TAVI service
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	yes

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	Standard procedural risks of TAVI apply

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Improved quality of life, reduced symptoms of breathlessness/heart failure, longer life
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	We do not know when patients have passed a point of no return regarding their ventricular function.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not really
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK. .

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help	1: Vahl TP, Thourani VH, Makkar RR, Hamid N, Khalique OK, Daniels D, McCabe JM, Satler L, Russo M, Cheng W, George I, Aldea G, Sheridan B, Kereiakes D, Golwala H, Zahr F, Chetcuti S, Yadav P, Kodali SK, Treede H, Baldus S, Amoroso N, Ranard LS, Pinto DS, Leon MB. Transcatheter aortic valve implantation in patients with high-risk symptomatic native aortic regurgitation (ALIGN-AR): a prospective, multicentre, single-arm study. Lancet. 2024 Apr 13;403(10435):1451-1459. doi: 10.1016/S0140-6736(23)02806-4. Epub 2024 Mar 26. PMID: 38552656.

	us if you list any that you think are particularly important.	2: Yokoyama H, Tamm AR, Geyer M, Munzel T, Treede H, von Bardeleben RS. Treatment of severe aortic valve regurgitation with the Trilogy TAVI system. EuroIntervention. 2023 Apr 24;18(17):1444-1445. doi: 10.4244/EIJ-D-22-00596. PMID: 36756786; PMCID: PMC10111118. 3: Baumbach A, Patel KP, Kennon S, Ozkor M, Mathur A, Huerta F, Tamm AR. A heart valve dedicated for aortic regurgitation: Review of technology and early clinical experience with the transfemoral Trilogy system. Catheter Cardiovasc Interv. 2023 Oct;102(4):766-771. doi: 10.1002/ccd.30795. Epub 2023 Aug 10. PMID: 37560819. 4: Adam M, Tamm AR, Wienemann H, Unbehaun A, Klein C, Arnold M, Marwan M, Theiss H, Braun D, Bleiziffer S, Geyer M, Goncharov A, Kuhn E, Falk V, von Bardeleben RS, Achenbach S, Massberg S, Baldus S, Treede H, Rudolph TK. Transcatheter Aortic Valve Replacement for Isolated Aortic Regurgitation Using a New Self-Expanding TAVR System. JACC Cardiovasc Interv. 2023 Aug 28;16(16):1965-1973. doi: 10.1016/j.jcin.2023.07.038. PMID: 37648344. 5: Poletti E, Adam M, Wienemann H, Sisinni A, Patel KP, Amat-Santos IJ, Orzalkiewicz M, Saia F, Regazzoli D, Fiorina C, Panoulas V, Brinkmann C, Giordano A, Taramasso M, Maisano F, Barbanti M, De Backer O, Van Mieghem NM, Latib A, Squillace M, Baldus S, Geyer M, Baumbach A, Bedogni F, Rudolph TK, Testa L. Performance of Purpose-Built vs Off-Label Transcatheter Devices for Aortic Regurgitation: The PURPOSE Study. JACC Cardiovasc Interv. 2024 Jul 8;17(13):1597-1606. doi: 10.1016/j.jcin.2024.05.019. PMID: 38986659.

19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Planned RCT vs Surgery
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	350
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Quality of life Rehospitalisation Mortality Adverse outcome measures: Emergency surgery Death

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Important new technology enabling us to treat previously undertreated patients

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Proctor for Jenavalve	**2023**	
Non-financial professional	PI for Relief AR study	**2023**	
Choose an item.			

x ☐ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Andreas Baumbach**
Dated:	**21-8-2024**

View results

Respondent

92 Anonymous

24:07
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1980 Transcatheter aortic valve implantation for aortic incompetence

Your information

2. Name: *

Dan Blackman

3. Job title: *

Consultant Interventional Cardiologist

4. Organisation: *

Leeds Teaching Hospitals NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Cardiovascular Intervention Society

7. Nominated/ratified by (if applicable):

British Cardiovascular Intervention Society

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 3564585

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes. I have performed approximately 2000 TAVI procedures, including around 50 TAVI procedures for aortic regurgitation

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

TAVI for aortic regurgitation is widely used, albeit in a relatively small proportion of patients compared to TAVI for aortic stenosis. Newer technology which is becoming available now, with dedicated devices designed for treating aortic regurgitation, will increase the use of TAVI for this indication, due to the far better outcomes achieved.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. Does this have a multi-indication?

No

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

Minor variation. It is basically the same procedure as TAVI, but potentially more challenging

18. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (●) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Addition to standard of care

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

Yes. Current TAVI devices designed for treating aortic regurgitation are associated with relatively poor outcomes. New devices designed specifically for AR, specifically the JenaValve Trilogy system, have shown fare superior outcomes

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

Currently patients with aortic regurgitation are treated by surgical AVR, or by TAVI if surgery is not possible

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

No

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Patients could be treated who have no other treatment option

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Yes. Patients who are unsuitable or high-risk for surgical aortic valve replacement

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Yes. TAVI is a much less invasive procedure than surgical AVR, and associated with shorter hospital stay. Patients not receiving any treatment for AR because they are not fit for surgery will potentially be saved from using hospital resources due to hospitalisation for heart failure

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    No change. All TAVI services would be able to do this

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Only to have some training when using dedicated new devices such as JenaValve

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Studies of TAVI for AR using conventional valves show 10% risk of valve embolisation, 10% second valve needed, 10% residual severe AR. However, outcomes with dedicated devices are much better and are similar to those for TAVI for severe AS

30. Please list the key efficacy outcomes for this procedure/technology?

    Procedural success. Technical success. Residual AR. Need for a 2nd valve. Mortality

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    Currently relatively little data from trials

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    Yes. Outcomes with different valve types. Larger studies needed

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

    - ( ) Most or all district general hospitals.
    - (•) A minority of hospitals, but at least 10 in the UK.
    - ( ) Fewer than 10 specialist centres in the UK.
    - ( ) Cannot predict at present.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    Lancet. 2024 Apr 13;403(10435) ALIGN-AR study

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    I do not know

36. Please list any other data (published and/or unpublished) that you would like to share.

    JACC Cardiovasc Interv. 2023 Aug 28;16(16):1965-1973

    JACC Cardiovasc Interv. 2023 Aug 28;16(16):1974-1985.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    500

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Procedural and technical success

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Adverse outcome measures.

    These should include early and late complications. Please state the post procedure timescales over which these should be measured:

    Mortality, residual AR, valve embolisation

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

None

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [x] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [ ] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

Speaker fees and honoraria for Medtronic, Abbott Vascular
Institutional research grant from Medtronic

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (•) I agree
- ( ) I disagree

Signature

44. Name: *

Daniel Blackman

45. Date: *

18/07/2024

View results

Respondent

2 Anonymous

62:31
Time to complete

1. Project Number and Name - (Can be found on email) *

IP1980

Your information

2. Name: *

Rajesh Kharbanda

3. Job title: *

Consultant Cardiologist

4. Organisation: *

Oxford University Hospitals NHS Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Cardiovascular Interventional Society

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

GMC 3580499

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

9. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

10. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Transcatheter aortic valve implantation (TAVI) is an established valve replacement procedure for aortic stenosis, but not currently indicated for aortic regurgitation. However, there are people with severe aortic regurgitation who cannot undergo surgery safely and in this situation TAVI can be considered. The TAVI devices used for aortic stenosis are not designed for treating aortic regurgitation and new devices are being developed for this purpose.

11. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

The procedure is not widely used at present because of the indications and the devices available. However, this is likely to increase as better devices become available. The condition is much less prevalent than aortic stenosis, so the numbers and speed of uptake will be slower than for TAVI.

The procedure is likely to be done in the established TAVI centres for adults.

The UK experience is limited because of technical issues with the TAVI devices available currently. Newer devices are in development to provide specific solutions for these patients.

12. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [x] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

13. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

14. Is the proposed indication appropriate? If not, please explain

Yes

15. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

This is an important innovation in the non-surgical treatment of aortic incompetence, particularly for people who cannot have surgery safely for whom no other option is available.

16. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

17. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

This has the potential to add an additional treatment option for patients with aortic incompetence, and to develop as a standard of care if appropriate evidence could be generated.

Current management

18. Please describe the current standard of care that is used in the NHS.

The current standard would be surgical aortic valve replacement and optimal medical therapy.

19. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

    If so, how do these differ from the procedure/technology described in the briefing?

    No

Potential patient benefits and impact on the health system

20. What do you consider to be the potential benefits to patients from using this procedure/technology?

    This procedure has the option to be a safe and effective treatment for aortic incompetence at lower risk than cardiac surgery. The situation is analogous to TAVI for aortic stenosis with shorter length of stay and quicker recovery.

21. Are there any groups of patients who would particularly benefit from using this procedure/technology?

    Aortic incompetence is a less prevent condition that aortic stenosis and has different causes. It is likely to benefit to those with heart failure and aortic incompetence most because the risk of surgery for these patients is higher than standard.

22. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Yes. This is a less invasive treatment and would reduce length of stay and need for cardiac intensive care support.

23. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    This procedure would be undertaken in TAVI centres. TAVI is undertaken in 33 sites across the UK. The capacity would need to be increased if this patient group were included.

24. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    The current devices have been used for TAVI and the developing devices for aortic incompetence are minor iterations on the current devices. The training in the use of these devices will be required.

Safety and efficacy of the procedure/technology

25. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    There are a number of reviews and opinion pieces on this area. The main issue is residual valve regurgitation, valve embolism (where the TAVI valve does not remain in the correct position), and the risks of TAVI including bleeding, stroke and death. The mortality rate in reported series so far is high but this may reflect the selective people treated. (https://doi.org/10.15420/icr.2021.19, https://www.youtube.com/watch?v=uFiyTg49eIg)

26. Please list the key efficacy outcomes for this procedure/technology?

Improvement in the degree of aortic incompetence. Improvement in left ventricular function. Improvement in heart failure symptoms. Improvement in survival.

27. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

There are no large trials testing the safety and efficacy of TAVI for aortic incompetence. It is a natural progression of TAVI to treat aortic incompetence after the success of TAVI for aortic stenosis, but the devices available are not ideally suited for this condition. Newer devices are being developed and evaluated in clinical practice.

28. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

29. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

30. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

31. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

No

32. Please list any other data (published and/or unpublished) that you would like to share.

N/A

Other considerations

33. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Approximately 250 people have been treated for AR with TAVI in the UK.

34. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

Device success (VARC criteria), number of devices used.
Degree of aortic incompetence after TAVI and changes in left ventricular size and function - echo 6 and 12 months
Heart failure symptoms. 6, 12, 36 and 60 months
Mortality
Stroke

35. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Procedural complications - bleeding, stroke, death. Device embolism, need for second device.
Late Mortality 12, 36 and 60 months
Pacemaker rate - in hospital

Further comments

36. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

There is not large study to inform the roll-out of TAVI for aortic incompetence.

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

37. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

38. Description of interests, including relevant dates of when the interest arose and ceased. *

Nil

39. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

40. Name: *

Rajesh Kharbanda

41. Date: *

12/05/2023

View results

Respondent

97 Anonymous

147:19
Time to complete

1. Project Number and Name - (Can be found on email) *

New Guidance in development: IP1980 Transcatheter aortic valve implantation for aortic incompetence

Your information

2. Name: *

Manoj Kuduvalli

3. Job title: *

Consultant Cardiac Surgeon

4. Organisation: *

Liverpool Heart and Chest Hospital NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Society for Cardiothoracic Surgery in Great Britain and Ireland

7. Nominated/ratified by (if applicable):

Society for Cardiothoracic Surgery in Great Britain and Ireland

8. Registration number (e.g. GMC, NMC, HCPC) *

5202440

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

I am familiar with the relatively small amount of literature published on this technology. TAVI for pure aortic incompetence is not a technology which is currently part of routine clinical practice in the UK or elsewhere.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

TAVI for pure AI is not part of routine clinical practice in the NHS yet. The technology has been evolving for a significant period of time and current worldwide literature is mainly limited to single centre or multicentre case series or registry data. The vast majority of these implants are 'off label' use of prostheses designed for use in aortic stenosis. There is only one CE approved valve available for on label use for pure aortic incompetence in the UK - the Jena Trilogy THV system. A previous version of this valve was available on a transapical deliver platform and this was withdrawn from the market in 2016. The currently available system is for a transfemoral approach and availability is limited to very few centres.

The procedure is usually performed by cardiologists. Patient selection is through MDTs which have cardiac surgeons in their membership

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [x] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes, it is appropriate in selected cases

16. Does this have a multi-indication?

No

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

The current gold standard for valve replacement for aortic incompetence is surgical aortic valve replacement. TAVI for pure AI is a novel approach and currently published results fail to reach the gold standard.

18. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- ( ) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- (•) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

This procedure does not have the potential to replace current standard of care. It would be used to treat a select group of patients with similar pathology

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

There have been recent developments in technology which has facilitated CE marking for on label use of the Jena Trilogy THV for on label use in the treatment of selected patients with pure aortic regurgitation

21. Do you think guidance would be helpful on this topic?

- (•) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

The current standard of care in intervention for severe pure aortic incompetence is surgical aortic valve replacement in most instances. In selected patients, surgical aortic valve repair may be considered in expert hands.

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

The available techniques are surgical aortic valve replacement (gold standard), surgical aortic valve repair (as above) and TAVI with either off label devices or more recently, on label devices

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

Surgical aortic valve replacement produces excellent outcomes, and has good published data with long term follow-up. TAVI in its current form for this pathology has potential use only in patients with prohibitive risk with surgical aortic valve replacement. Appropriate use of TAVI for AI in this select group of patients will allow them benefit from aortic valve intervention compared to simply being on best medical therapy (which has poor outcomes in the medium and long term)

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patients with pure aortic incompetence who would benefit from valve intervention but are at prohibitive or very high risk if they were to undergo surgical aortic valve intervention

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

Judicious use of this procedure in the correct group of patients as described above would result in improved outcomes including a survival benefit for patients, improved quality of life and reduced hospital admissions with heart failure.

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

The clinical facilities required to deliver this procedure are the same as are required for deliver TAVI for severe aortic stenosis. These facilities are widely available already in the NHS.

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

Current TF TAVI operators would need to undergo bespoke training in devices suitable for this procedure to ensure safe practice. The MDTs contributing to choosing the appropriate patients for this procedure also need to be suitably educated in the current state of technology and evidence for this procedure

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

- Adverse events reported in the literature (if possible, please cite literature)
- Anecdotal adverse events (known from experience)
- Theoretical adverse events

Apart from femoral access complications, previous off label use of devices designed for use in aortic stenosis have recorded a higher rate of complications when used for pure aortic incompetence. These complications include valve migration / embolization, permanent pacemaker, residual aortic incompetence and annular rupture. Technical and procedures success rates have been considerable lower than when used for aortic stenosis. Recent data using on label Jena Trilogy THV from the ALIGN-AREFS trial presented in 2023 has achieved considerably better success rates and lower complication rates compared to previous off label use data.

30. Please list the key efficacy outcomes for this procedure/technology?

Technical and procedural success
Procedural mortality
1 year mortality
Residual aortic incompetence
Periprocedural permanent pacemaker (PPM) rate
Incidence of significant complications such as annular rupture, valve migration / embolization, coronary obstruction, stroke, vascular access complications

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

Previously published data on success rates and complication rates with off label use have been of concern, hence their use has been limited to a very small cohort of patients. Recent data from on label use has been more encouraging.

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

There is still uncertainly about its efficacy and safety if it were to be expanded to widespread use

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

Early feasibility study of the transfemoral Trilogy THC system in AI cases at high risk for open surgical replacement and without congenital bicuspid or unicuspid valve morphology, the ALIGN-AREFS trial (conducted in Germany, the Netherlands and the USA) was presented as a late-breaking trial at the TCT meeting in October 2023

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

As above

36. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

Difficult to estimate at this stage as it is not clear which sub-cohort of patients with severe pure aortic incompetence would be deemed eligible for this procedure. It will depend on safety and efficacy data both worldwide and in the UK

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Beneficial outcome measures.

These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

1 year and 5 year survival
Quality of life evaluation post-procedure

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Periprocedural and early mortality
Procedural complications as listed previously (and below)

Residual aortic incompetence
Periprocedural permanent pacemaker (PPM) rate
Incidence of significant complications such as annular rupture, valve migration / embolization, coronary obstruction, stroke, vascular access complications

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

Nil else to add to previously articulated

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

No interests to declare

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Manoj Kuduvalli

45. Date: *

29/07/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1980 Transcatheter aortic valve implantation for aortic incompetence**

Your information

Name:	Dr Mohammad Alkhalil
Job title:	Consultant Cardiologist
Organisation:	Britiash Cardiovascular Society
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Click here to enter text.
Nominated/ratified by (if applicable):	Dr Alexandra Thompson
Registration number (e.g. GMC, NMC, HCPC)	6152959

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

☐ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice.

☒ I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. If consent is NOT given, please state reasons below:

Click here to enter text.

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Yes, I have performed trans-catheter aortic valve implantations for patients with native aortic regurgitation.
	Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	The procedure is not widely used in the NHS and remains reserved for patients who have prohibitive or high surgical risk with consensus from the MDT. Patients with suitable anatomy would certainly benefit from expanding this technology
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	No
	– If your specialty is involved in patient selection or referral to another specialty for this	Patients are usually referred for surgical AVR. Should they get turned down, then percutaneous option is sought

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure.
3	Does the title adequately reflect the procedure? How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	**Transcatheter aortic valve implantation for native aortic incompetence** We are currently using trans-catheter heart valves that are not designed to manage native aortic incompetence. Advances in technology would allow new valves to better treat this issue. Definitely novel and of uncertain safety and efficacy.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Additional to existing standard care
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed	Yes- there are new trans-catheter valves that are specifically designed to address aortic incompetence. However, accessing these valves is not straightforward and appears to be limited to certain centres.

	substantially since publication of the guidance?	There is limited data on the safety of this procedure and no head-to-head comparison with surgical AVR (standard care)

Current management

6	Please describe the current standard of care that is used in the NHS.	Surgical AVR
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	No

Potential patient benefits and impact on the health system

8	What do you consider to be the potential benefits to patients from using this procedure/technology?	Avoid surgical procedures, shorter in-hospital stay and quicker recovery for patients
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	High risk surgical patients
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes Less invasive treatment with shorter ITU, and overall in-hospital stay.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No change- procedures could be done in the cathlab
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Familiarities with new or existing valves

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	Left ventricular migration leading to severe aortic incompetence.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Re admission with heart failure
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Ability of the trans-catheter heart valve to stay in position after deployment. New trans-catheter heart valves have been modified to overcome this issue
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	As above
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Cannot predict at present.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help	Align-AR pivotal. J-valve North American safety study

	us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	
20	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	10-15% of patients undergoing surgical AVR
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Readmission with heart failure Adverse outcome measures: Residual aortic incompetence

Further comments

23	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	

NICE National Institute for Health and Care Excellence

Declarations of interests

Please state any potential conflicts of interest relevant to the procedure/technology (or competitor technologies) on which you are providing advice, or any involvements in disputes or complaints, in the previous **12 months** or likely to exist in the future. Please use the NICE policy on declaring and managing interests as a guide when declaring any interests. Further advice can be obtained from the NICE team.

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.			
Choose an item.			
Choose an item.			

☒ I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website.

Print name:	**Dr Mohammad Alkhalil**
Dated:	**26.7.2023**

View results

Respondent

98 Anonymous

23:14
Time to complete

1. Project Number and Name - (Can be found on email) *

Transcatheter aortic valve implantation for aortic incompetence (IP1980)

Your information

2. Name: *

Tom Cahill

3. Job title: *

Consultant Structural & Interventional Cardiologist

4. Organisation: *

Oxford University Hospitals NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

8. Registration number (e.g. GMC, NMC, HCPC) *

6164179

9. I confirm that:

- I am a registered practising professional in the UK/NHS and in good professional standing
- I have specialist knowledge in the technology or disease area
- I will declare all conflicts of interest in relation to the technology under consideration
- I will abide by NICE's governance policies and comply with NICE's processes and methods
- I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

Personal data submitted to NICE can be used for the purposes of carrying out its CHTE outputs. Personal data will be held on NICE's databases and I may be contacted in the future by NICE after the completion of this topic. *

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

The information that you provide on this form will be used to develop guidance on this procedure.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

For more information about how we process your data please see our privacy notice: https://www.nice.org.uk/privacy-notice

10. I give my consent for the information in this questionnaire to be used and may be published on the NICE website as outlined above. *

- (●) I agree
- ( ) I disagree

The procedure/technology

Please answer the following questions as fully as possible to provide further information about the procedure/technology and/or your experience.

11. Please describe your level of experience with the procedure/technology, for example:

Are you familiar with the procedure/technology?

Yes - I have extensive experience with transcatheter aortic valve implantation (TAVI), including in patients with aortic incompetence/regurgitation. I am a current user/implanter of Jenavalve, which is the only dedicated transcatheter heart valve for use in aortic regurgitation.

12. Have you used it or are you currently using it?

- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?

- Is this procedure/technology performed/used by clinicians in specialities other than your own?

- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.

TAVI for aortic incompetence/regurgitation is likely to increase substantially with the availability of dedicated transcatheter devices (specifically Jenavalve). This valve is currently in use in 3 UK centres (Oxford, Leeds, Barts) but is likely to roll out in most TAVI centres over the next 5 years. My specialty of structural intervention is directly involved in patient work-up, selection and follow-up.

13. Please indicate your research experience relating to this procedure (please choose one or more if relevant):

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [x] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

15. Is the proposed indication appropriate? If not, please explain

Yes

16. Does this have a multi-indication?

Yes - mixed aortic valve disease (stenosis and regurgitation)

17. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?

It is a novel valve design and implant technique but the overall procedural steps and concept are very similar to TAVI for aortic stenosis

18. Which of the following best describes the procedure:

- ( ) Established practice and no longer new.
- (•) A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.
- ( ) Definitely novel and of uncertain safety and efficacy.
- ( ) The first in a new class of procedure.

19. Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?

Addition to standard of care (surgery)

20. Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?

No

21. Do you think guidance would be helpful on this topic?

- (●) Yes
- ( ) No

Current management

22. Please describe the current standard of care that is used in the NHS.

Surgical aortic valve replacement - for patients fit for surgery
Medical therapy (diuretics, palliation) - for patients unfit for surgery

23. Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this?

If so, how do these differ from the procedure/technology described in the briefing?

Existing TAVI valves can (sometimes) be used 'off label' for patients with aortic regurgitation - but the risk is high as they are not designed for this indication. Dedicated transcatheter heart valve devices for aortic regurgitation such as Jenavalve have the potential to revolutionise the approach to aortic regurgitation in patients who are not fit for surgical aortic valve replacement

Potential patient benefits and impact on the health system

24. What do you consider to be the potential benefits to patients from using this procedure/technology?

There are potential enormous benefits to patients who are at high surgical risk and cannot undergo surgery. TAVI is a low risk, straightforward, predictable procedure with excellent outcomes and an easy recovery. TAVI in aortic regurgitation provides highly effect symptom relief (and likely substantial prognostic benefit)

25. Are there any groups of patients who would particularly benefit from using this procedure/technology?

Patients unfit for cardiac surgery

26. Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?

    Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?

    Yes. Patients at high risk for surgery (who otherwise have a prolonged intensive care stay and difficult recovery) can be treated by a low risk, transcatheter approach with a short length of stay and rapid recovery

27. What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?

    Increased cardiac catheterisation laboratory time/infrastructure

28. Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?

    Training on the Jenavalve system

Safety and efficacy of the procedure/technology

29. What are the potential harms of the procedure/technology?

    Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:

    - Adverse events reported in the literature (if possible, please cite literature)
    - Anecdotal adverse events (known from experience)
    - Theoretical adverse events

    Permanent pacemaker requirement (15-20%)
    Stroke (1-2%)
    Vascular access complications (5%)
    Death (1-2%)

    See ALIGN-AR: https://www.sciencedirect.com/science/article/abs/pii/S0140673623028064

30. Please list the key efficacy outcomes for this procedure/technology?

    Survival to hospital discharge
    Survival at 30 days/1 year
    Freedom from heart failure hospitalisation/readmission
    Symptom status (breathlessness, exercise tolerance)
    Quality of life

31. Please list any uncertainties or concerns about the efficacy and safety of this procedure/technology?

    Long-term durability of valve function is not yet established

32. Is there controversy, or important uncertainty, about any aspect of the procedure/technology?

    Need for RCT data for TAVI compared with surgical aortic valve replacement in patients fit for surgery

33. If it is safe and efficacious, in your opinion, will this procedure be carried out in:

- ○ Most or all district general hospitals.
- ◉ A minority of hospitals, but at least 10 in the UK.
- ○ Fewer than 10 specialist centres in the UK.
- ○ Cannot predict at present.

Abstracts and ongoing studies

34. Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work).

    Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.

    https://www.sciencedirect.com/science/article/abs/pii/S0140673623028064

35. Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.

    There are plans for a RCT of Jenavalve vs surgical AVR but to my knowledge this study has not yet started

36. Please list any other data (published and/or unpublished) that you would like to share.

Other considerations

37. Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?

    Across all 35 TAVI centres, I would estimate 10-20 per year per centre, i.e around 700

38. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

    Beneficial outcome measures.

    These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured.

    Patient quality of life scoring KCCQ
    Patient symptom status
    Patient 6 minute walk distance (exercise capacity)

39. Please suggest potential audit criteria for this procedure/technology. If known, please describe:

Adverse outcome measures.

These should include early and late complications. Please state the post procedure timescales over which these should be measured:

Permanent pacemaker implantation rate
Stroke rate (in hospital)
Death at 30 days
Death at 1 year

Further comments

40. If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe *

There would be substantial value to an RCT of TAVI for aortic regurgitation vs surgical aortic valve replacement in patients at moderate or high surgical risk. Enrolling younger patients with AR for treatment by TAVI is also of importance, as there are important unanswered questions about the durability of transcatheter heart valves (compared with surgical valves).

Declarations of interests

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41. Type of interest: *

- [ ] Direct: financial
- [ ] Non-financial: professional
- [ ] Non-financial: personal
- [ ] Indirect
- [x] No interests to declare

42. Description of interests, including relevant dates of when the interest arose and ceased. *

None

43. I confirm that the information provided above is complete and correct. I acknowledge that any changes in these declarations during the course of my work with NICE, must be notified to NICE as soon as practicable and no later than 28 days after the interest arises. I am aware that if I do not make full, accurate and timely declarations then my advice may be excluded from being considered by the NICE committee.

Please note, all declarations of interest will be made publicly available on the NICE website. *

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Tom Cahill

45. Date: *

01/08/2024