View results

Respondent

1 Anonymous

1399:18
Time to complete

Your information

1. Name: *

J Andreas Hoschtitzky

2. Job title: *

Consultant Paediatric and Adult Cardiac Surgeon

3. Organisation: *

Royal Brompton Hospital, part of Guy's and St. Thomas' Foundation Trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

GMC, SCTS

6. Nominated/ratified by (if applicable):

BCCA

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

4281399

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

8. 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.

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

   Are you familiar with the procedure/technology?

   Yes, I have learned from the expert in the Ozaki procedure and been involved in a few cases

10. 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.

    Not currently using it
    This is used sporadically by clinicians in my speciality

11. 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

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

13. 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 relatively new procedure that has been performed in a single institution in Japan for 20 years and over the past 5 years been used variably by a few institutions around the world

14. 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.

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

Potentially if it proves durability and reproducibility then it may become an important adjunct in clinical practice

Current management

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

aortic valve replacement either with biological valves or mechanical valves or the Ross procedure

17. 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

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

additional technique to preserve partially native valves, perform reproducible alternatives to current valve replacement options that are not durable or have long-term complication rates

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

children and younger adult patients with aortic regurgitation or mixed valve laesions who have not had previous surgery and native pericardium

20. 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?

    more valve disease options, possible better gradients and less ventricular dysfunction compared with prosthetic valves

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

    standard, in addition to extractor hoods for gluteraldehyde and commercially available templates for cutting the leaflets from the pericardium

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

    yes, for the surgical technique with Prof Ozaki

Safety and efficacy of the procedure/technology

23. 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

    Early fibrosis of the leaflets, we have had in our institution 1 patient who developed a thrombus on of the leaflets within a year of the procedure, early failure and regurgitation of the newly constructed aortic valve.

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

Durability of the valve, freedom of symptoms and freedom of reintervention and death, freedom of thrombo-embolism

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

see above, and reproducibility of the technique in children and adults

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

yes, so far some concerns about durability/freedom from reintervention and reproducibility, issues to do with the preparation of pericardium in view of need for extractor hoods in theatre in view of UK laws around use of gluteraldhyde

27. 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

28. 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.

    standard searches

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

    no

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

Other considerations

31. 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)?

    in the UK possibly up to 100-150 patients per year minimum

32. 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.

freedom from reintervention and death and complications, 1-5-10 years, symptoms of breathlessness/angina/syncope/pre-syncope, LV function, gradients across the LVOT, degree of stenosis or regurgitation

33. 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:

death, stroke, thrombo-embolism, reintervention, echo parameters, see above

Further comments

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

There needs to be a clear pathway and inclusion and exclusion criteria for patients who would be appropriate for this procedure. A parallel track of a RCT needs to happen comparing it either to Ross or valve repair or valve replacement

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.

35. Type of interest: *

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

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

none

37. 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

38. Name: *

J. Andreas Hoschtitzky

39. Date: *

06/12/2022

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: Aortic valve reconstruction with glutaraldehyde-treated autologous pericardium (IP1359)

Your information

Name:	Massimo Caputo
Job title:	BHF Professor of Cardiac Surgery
Organisation:	University of Bristol
Email address:	[redacted]
Professional organisation or society membership/affiliation:	RCS; ESCTS; SCTS UK and Ireland; BCCA; SCV
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 4077976

How NICE will use this information: the advice and views given in this questionnaire will form part of the information used by NICE and its advisory committees to develop guidance or a medtech innovation briefing on this procedure/technology. Information may be disclosed to third parties in accordance with the Freedom of Information Act 2000 and the Data Protection Act 2018, complying with data sharing guidance issued by the Information Commissioner's Office. 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 the process 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:

☐ Yes

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

Please note that questions 10 and 11 are applicable to the Medical Technologies Evaluation Programme (MTEP). We are requesting you to complete these sections as future guidance may also be produced under their work programme.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am very familiar and performed more than 50 Ozaki procedures in UK and starting using it in my missions in developing countries in patients with congenital or rheumatic valve disease
	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	I am still using it especially in young adults who do not want a mechanical valve or a Ross procedure and biological valve are not ideal; It is not used widely in the UK; I have trained 3 surgeons in Bristol with the Ozaki procedure; The procedure is only performed by cardiac surgeons; we are involved in patients selection together with the cardiologist and cases are discussed at multidisciplinary meetings.

	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. All of the above (I am submitting a study for following up these patients with MRI and CT PET scans)
3	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):	Definitely novel (very good early and 3-4 years follow up result in UK and Europe but lacking 10 year follow up apart from the Japan data)
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?	I believe so especially in specific population

Current management

5	Please describe the current standard of care that is used in the NHS.	Standard care is using a biological valve (in young adult not a good option as it is now clear from literature that impact on survival)
6	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 Ross procedure would be the gold standard for young adult (<50 years) but it is performed by very few surgeons and much more complex. In my practice Ross procedure remain plan A for young adult with aortic valve disease and Ozaki plan B.

Potential patient benefits and impact on the health system

7	What do you consider to be the potential benefits to patients from using this procedure/technology?	Better survival and valve related complications
8	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Young adult <50 years of age Patients with rheumatic fever Patients with contraindication to anticoagulation Teen agers when the Ross procedure is not doable
9	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
10 - MTEP	Considering the care pathway as a whole, including initial capital and possible future costs avoided, is the procedure/technology likely to cost more or less than current standard care, or about the same? (in terms of staff, equipment, care setting etc)	Less
11 - MTEP	What do you consider to be the resource impact from adopting this procedure/technology (is it likely to cost more or less than standard care, or about same-in terms of staff, equipment, and care setting)?	Avoiding prosthetic valve in young patients will reduce medical treatment and readmission to hospitals

12	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No special changes required
13	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, the first 5-6 cases need mentoring from experienced surgeons

Safety and efficacy of the procedure/technology

14	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	The valve reconstruction is not successful, and patient might need a prosthetic valve (this is normally done at the same operation so does prolong the operation slightly but with minimal risk) Infective endocarditis (this is a potential complications for any cardiac procedure and in fact using prosthetic valves increases the risk of endocarditis while having autologous pericardium in the aortic position would decrease it) Failure of the valve at follow up (this has been noted in the very young population 5-10 yrs old as in same cases the leaflets have calcified) Embolization (in theory but not reported)
15	Please list the key efficacy outcomes for this procedure/technology?	Early and long term durability of the valve Evidence of less calcification of the leaflets compared to bio-prosthetic valve Avoid the use of Warfarin
16	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	In some bicuspid aortic valve with very asymmetric sinuses, it is difficult to size the leaflets
17	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Long term follow up in Europe and US but available in Japan

18	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 (at least as the initial experience but then it can be expanded)

Abstracts and ongoing studies

19	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.	There have been quite a lot of publications fully available on Pubmed These are from the Bristol team 1. Elliott D, Ochieng CA, Zahra J, McNair AGK, Main BG, Skilton A, Blencowe NS, Cousins S, Paramasivan S, Hoffmann C, Donovan JL; Lotus clinical innovator collaborators. What are Patients told about Innovative Surgical Procedures? A Qualitative Synthesis of Seven Case Studies in the UK. Ann Surg. 2022 Sep 30. doi: 10.1097/SLA.0000000000005714. Online ahead of print. 2. Benedetto U, Sinha S, Dimagli A, Dixon L, Stoica S, Cocomello L, Quarto C, Angelini GD, Dandekar U, **Caputo M.** Aortic valve neocuspidization with autologous pericardium in adult patients: UK experience and meta-analytic comparison with other aortic valve substitutes. Eur J Cardiothorac Surg. 2021 Jan 31:ezaa472. doi: 10.1093/ejcts/ezaa472. Online ahead of print 3. Shearn AIU, Ordoñez MV, Rapetto F, **Caputo M**, Biglino G. Rapid prototyping flexible aortic models aids sizing the valve leaflets and planning the Ozaki repair. JACC Case Rep. 2020 Jul;2(8):1137-1140.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	There is a new AV/Neo Registry led by Boston Children/Harvard Med school; so far 500 pts have been included from 15 institution. We have started the Lotus study in Bristol for surgical evaluation of new techniques https://www.bristol.ac.uk/population-health-sciences/centres/surgical-research/research/surgical-innovation/

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)?	This depends on the indication and the number of surgeons adopting the technique Could be 1000 per year in the UK.
22	Are there any issues with the usability or practical aspects of the procedure/technology?	None
23	Are you aware of any issues which would prevent (or have prevented) this procedure/technology being adopted in your organisation or across the wider NHS?	None
24	Is there any research that you feel would be needed to address uncertainties in the evidence base?	Evidence that these autologous pericardial leaflets have less degeneration at follow up compared to the standard bioprosthetic valves and better haemodynamic (this last one impact on patients' survival)
25	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	Beneficial outcome measures: 1) MRI and echo evidence of aortic valve haemodynamic and function 2) CT PET evidence of no calcification These should be measured at mid follow up 3-5 years 3) Valve related events (thromboembolic or haemorrhagic events, endocarditis, severe valve dysfunction) 4) Survival 5) Quality of life questionnaire These should be measured at long -term follow up

	complications. Please state the post procedure timescales over which these should be measured:	
26	Is there any other data (published or otherwise) that you would like to share with the committee?	Lotus study in Bristol (see web site) https://www.bristol.ac.uk/population-health-sciences/centres/surgical-research/research/surgical-innovation/

Further comments

26	Please add any further comments on your particular experiences or knowledge of the procedure/technology,	I feel this is an excellent procedure for surgeons to have in their armamentarium and dealing with young adult requiring AVR; young patients (<50-55) should all been given the full option of valve replacement and repair (including Ross procedure, Ozaki or prosthetic valves)

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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.	None		
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:	**Massimo Caputo**
Dated:	**30/11/2022**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1359 Aortic valve reconstruction with glutaraldehyde-treated autologous pericardium**

Your information

Name:	Mohamed Nassar
Job title:	Consultant Paediatric and Adult Congenital Cardiac Surgery
Organisation:	Newcastle upon Tyne NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	GMC SCTS
Nominated/ratified by (if applicable):	BCCA
Registration number (e.g. GMC, NMC, HCPC)	7242179

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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☒ 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 have introduced the procedure to the trust after approval of the new intervention committee in 2018. I have been proctored by Prof. Ozaki for the first few cases and then I led the Ozaki (Aortic valve reconstruction) program in our trust since that date. We are currently offering the procedure to our paediatric and adult congenital patients. The procedure is being used in other congenital units across the UK and I have been chosen to proctor colleagues in other trust where the procedure is being introduced
	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?	The procedure is used for aortic valve replacement in congenital and adult acquired patients. No speciality other than Cardiothoracic surgery is using this procedure

	– If your specialty is involved in patient selection or referral to another specialty for this 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 clinical research on this procedure involving patients or healthy volunteers.
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):	YES . The use of pericardium in repair/reconstruction of the aortic valve is not new but the technique in this procedure (Ozaki aortic reconstruction) is relatively new 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?	An addition to existing standard care

Current management

6	Please describe the current standard of care that is used in the NHS.	The surgical options for aortic valve pathology are either valve repair or replacement. Valve repair may involve leaflet augmentation with additional material (autologous or bovine pericardium). When repair is not feasible, replacement becomes the only option with either mechanical valve (requiring life-long anti-coagulation with all the anti-coagulation related problems) or tissue valves (animal origin) that will degenerate with time and require redo replacement (much earlier in younger patients)
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?	Paediatric and adult patients with aortic valve disease requiring aortic valve replacement
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Children and young adults with aortic valve disease
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, using this technology as an alternative to mechanical valve replacement would avoid the use of anti-coagulation with all its related morbidities and need to attend anti-coagulation clinics for regular follow up
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	There is a single-use template pack that is used for each patient .
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, Dry lab and proctoring for the first few cases is required

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:	Possible adverse events: (low incidence) Technical failure requiring early re-intervention Clot formation and embolisation

	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?	An addition to the present aortic valve replacement options especially in children and young adults as there is no option that provides life long solution and multiple operations on the valve are usually anticipated
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Long-term outcome is not clear yet. Initial single centre results are promising but long-term data is not available yet
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Long-term outcome and the need for initial anti-coagulation to avoid any embolization and improve durability
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 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 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)?	Difficult to estimate
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:	In hospital mortality. Surgery related morbidity (need for pacemaker, neurological complications, blood transfusion) Freedom from re-operation (mid and long term) Freedom from anti-coagulation related complications Incidence of endocarditis

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.			

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

Print name:	**Mohamed Nassar**
Dated:	**10/12/2022**

View results

Respondent

2 Anonymous

53:51
Time to complete

Your information

1. Name: *

Norman Briffa

2. Job title: *

Consultant cardiothoracic Surgeon

3. Organisation: *

Sheffield teaching Hospitals NHS trust

4. Email address: *

[redacted]

5. Professional organisation or society membership/affiliation: *

British Heart Valve Society & British Cardiac Society

6. Nominated/ratified by (if applicable):

BHVS

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

2805300

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.

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8. 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.

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

   Are you familiar with the procedure/technology?

   yes

10. 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.

    Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? - No. No procedure specific register exists but useful information may be available in NACSA (national adult cardiac surgery audit - compulsory)

11. 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.
- [x] I have had no involvement in research on this procedure.
- [x] research prior to submitting to NICE as OZAKI pr

12. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

13. 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 a Novel approach to treating aortic valve disease

14. 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.

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

an addition to existing standard care

Current management

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

aortic valve replacement with an 'on the shelf' Tissue or mechanical prosthesis

17. 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?

Aortic Valve repair in certain cases of pure aortic regurgitation

Potential patient benefits and impact on the health system

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

solution using autologous tissue which may be durable and which obviates the need for anticoagulation

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

Younger patients with aortci valve disease

20. 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?

    Possibly by removing need for warfarin and INR monitoring

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

    none apart from availability of weak glutaraldehyde solution in the operating room

22. 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

23. 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

    Endocarditis, need for redo surgery in early or late phases, increased risk of postoperative aortic regurgitation

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

    Competent prosthesis with low gradient as measured on echocardiography

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

    uncertainty about durability

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

    see above - durability

27. 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

28. 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://doi.org/10.1016/j.ahj.2022.09.003
    https://doi.org/10.1111/jocs.16846
    https://doi.org/10.1007/s40140-021-00454-5

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

    not to my knowledge

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

    nil

Other considerations

31. 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)?

    pre COVID around 1000 patients underwent isolated AVR every year in the UK

32. 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.

    Transthoracic echo outcomes including LV function and gradients across AV, Euroqol and Minnesota Living with Heart failure at 3-6 months, 12 months later and at 5 years.

33. 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:

    30 day, 1,2 and 5 year mortality and 1,2,5 year re-hospitalisation

Further comments

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

Set up of a registry, an NIHR funded RCT comparing this to standard practice with outcomes mentioned previously

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.

35. Type of interest: *

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

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

BHVS Emeritus President,
NICE Adult heart Valve Disease Committee Member,
Associate Editor Heart journal

37. 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

38. Name: *

Norman Briffa

39. Date: *

08/12/2022