NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP2009 Tricvalve Bi-caval valve implantation for Edge 2 Edge repair**

Your information

Name:	Angel Sánchez Recalde
Job title:	Interventional Cardiologist
Organisation:	Ramon y Cajal University Hospital
Email address:	
Professional organisation or society membership/affiliation:	Spanish Society of Cardiology
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text.

How NICE will use this information:

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

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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

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? 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 familiar with the procedure; I have personally performed 15 procedures and assisted as a proctor in over 40 procedures. I have implanted Tricvalve bi-caval prostheses at my hospital in Madrid and have assisted as a proctor in multiple countries around the world. The procedure is performed by a team consisting of interventional cardiologists, specialists in cardiovascular imaging, and anesthesiologists. Clinical cardiologists and specialists in valvular heart diseases and heart failure are the ones performing patient selection and referring patients for Tricvalve bi-caval interventions

	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 with tricuspid regurgitation treated with Tricvalve system. It is the largest registry with data on this technology, and I have the preliminary analyses. Also, I am a co-author of three publications on this technology.
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, Tricvalve bi-caval valve implantation for patients with severe, symptomatic tricuspid regurgitation. The indications are: severe symptomatic tricuspid regurgitation, NYHA class III-IV or right heart failure during the last 12 months despite optimal medical treatment. It is a novel approach to treat the deleterious effects of tricuspid regurgitation implanting 2 valves in the superior and inferior vena cava. We have data about the 30-day safety and 12-month efficacy outcomes of the TricValve system, a dedicated transcatheter bi-caval stent comprised of specifically designed bioprosthetic valves for the superior and inferior vena cava. Established practice and no longer new.
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?	It is used as an addition or alternative standard of 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 substantially since publication of the guidance?	No substantial modifications in the procedure technique. No changes after CE approval with the TRICUS Euro study.

Current management

6	Please describe the current standard of care that is used in the NHS.	This device is not used in the NHS
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 competing or alternative procedure. There are cases that are not suitable for tricuspid valve repair or ortothopic valve replacement, and heterotopic valves with Tricvalve is the only alternative.

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?	Improvement in functional class, quality of life, exercise capacity, and peripheral congestion
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	High surgical risk patients, not candidates for edge-to-edge therapy or percutaneous annuloplasty
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?	This therapy reduces the rate of rehospitalizations
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	This technique does not need special facilities.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	This technique is a feasible and a safe option to treat a broad range of patients with severe tricuspid regurgitation

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:	Shoulder pain (60%), major bleeding (10-20%), right heart thrombi (5-13%)

	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?	TricValve system is associated with meaningful 1-year clinical improvements in terms of QOL, functional class and peripheral congestion
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
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.	TRICUS registry
20	Please list any other data (published and/or unpublished) that you would like to share.	Tric-Bicaval registry

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)?	
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, functional class and peripheral congestion Adverse outcome measures: Transient shoulder pain (immediately after procedure), bleeding (after procedure), paravalvular leak (after procedure), mortality, renal dysfunction, re-hospitalizations (3-12 months), leaflet thrombosis

Further comments

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

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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
Direct - financial	Proctoring procedures “Products and Features”	**2019**	**Until now**
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:	**Angel Sánchez Recalde**
Dated:	**31-Jan-2024**

View results

Respondent

47 Anonymous

14:18
Time to complete

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

IP2009

Your information

2. Name: *

HAGENSTEIN ALEXIS

3. Job title: *

Sr Manager, Market Access EMEACLA

4. Organisation: *

Edwards Lifesciences

5. Email address: *

6. Professional organisation or society membership/affiliation: *

None

7. Nominated/ratified by (if applicable):

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

Industrial

How NICE will use this information:

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

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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?

    Not familiar with the technology but heard of it

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.

    No

12. 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

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?

Novel innovative approach versus standard of care (which remains the optimal medical treatment for isolated severe TR).

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 procedure will be used in addition to existing standard of care and other transcatheter interventons for TR currently under clinical investigation (tricuspid transcatheter edge-to-edge repair, transcatheter tricuspid replacement).

Current management

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

Optimal medical treatment based mainly on diuretics. Surgical treatment is not used broadly as it is associated with an high in-hospital mortality (8-10%) for isolated severe TR.

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?

Transcatheter edge-to-edge repair (TriClip or PASCAL), transcatheter tricuspid annuloplasty (CARDIOBAND) or transcatheter tricuspid orthotopic valve replacement valve replacement (EVOQUE).

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?

Reducing TR, improving quality of life, improving functional status, improving survival, reduce HF-hospitalization.

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

Patient with severe TR, not eligible to surgery and in whom no other therapeutic alternatives exists.

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, fewer hospital visits.

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

More cathlab.

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

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

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

    TR reduction.

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

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.

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

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)?

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.

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:

Further comments

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

Need for further research.

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

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

Part of Edwards Lifesciences, industrial competitor.

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: *

    Alexis Hagenstein

41. Date: *

    14/11/2023

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP2009 Bicaval valve implantation for tricuspid regurgitation**

Your information

Name:	Jonathan Byrne
Job title:	Consultant Cardiologist
Organisation:	King's College Hospital
Email address:	
Professional organisation or society membership/affiliation:	BCIS
Nominated/ratified by (if applicable):	BCIS
Registration number (e.g. GMC, NMC, HCPC)	4183161

How NICE will use this information:

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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 do not carry out the procedure but am familiar with the technology and have experience in the reatment of severe tricuspid regurgitation using other percutaneous techniques, particularly transcatheter edge to edge repair.
	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?	I am aware that the use if this technology is extremely limited at present in the UK, with experience limited to only a handful of cases.
	– Is this procedure/technology performed/used by clinicians in specialities other than your own?	This procedure is not carried out by clinicians in specialties other than my own
	– If your specialty is involved in patient selection or referral to another specialty for this	I am involved in the selection of patients for percutaneous treatment for tricuspid valve disease.

	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? 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 use of a bicaval valve to treat severe tricuspid regurgitation is a novel concept to treat/mitigate the effects of severe tricuspid regurgitation. 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?	As an addition to standard care
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	No

	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	
		No previous guidance on the topic has been published by NICE

Current management

6	Please describe the current standard of care that is used in the NHS.	Medical therapy is the standard of care for the vast majority of patients with severe tricuspid regurgitation. Surgical repair of the tricuspid valve is suitable in a very small number of cases.
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 other procedure has a similar mode of action to the bicaval valve. There are, however, other competing percutaneous techniques which are used to treat severe tricuspid regurgitation, namely transcatheter edge to edge repair.

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?	Symptomatic benefit/quality of life improvement in a patient population with limited treatment options available
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patient with severe/torrential tricuspid regurgitation who are unsuitable for surgery or other percutaneous techniques,
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?	In theory, this technology could reduce the frequency of hospital visits for patients with severe tricuspid regurgitation and improve quality of life.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	This procedure can be carried out in existing facilities
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	The procedure needs specific training/proctoring to allow it to be carried out safely.

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:	Complications of the procedure include vascular injury/bleeding and rhythm disturbance and potentially thrombosis on the device. Theoretical risk of conversion to open surgery (sternotomy and tricuspid valve repair) Death is a potential, but rare complication The frequency of these adverse events is low in the (limited) number of reported cases

	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?	Quality of life improvement (KCQ scores) New York Heart Association functional Class Nt proBNP levels
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	To date, the evidence for efficacy and safety of the device is limited to small number of single arm studies.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The single arm studies to date have reported improvement in quality of life and functional heart failure class. There are no randomised data comparing treatment with standard (meducal) care and no hard outcome data exists for the device
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 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.	Not to my knowledge
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)?	5-10 per centre
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	Beneficial outcome measures: Quality of life questionaires NYHA class pre and post procedure Diruetic therpay use NT pro BNP levels Adverse outcome measures:

	complications. Please state the post procedure timescales over which these should be measured:	Procedural success Conversion to open surgery Bleeding rates/vascular complictions Stroke- 30 day and 1 year

Further comments

23	If you have any further comments (eg. issues with usability or implementation, the need for further research), please describe.	Further research required. Current studies are small and non -randomised with no comparator group.

NICE National Institute for Health and Care Excellence

Declarations of interests

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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:	**Jonathan Byrne**
Dated:	**16th October 2023**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP2009 Tricvalve Bi-caval valve implantation for Edge 2 Edge repair**

Your information

Name:	Prof Keith G Oldroyd
Job title:	Chief Medical Officer
Organisation:	Biosensors International
Email address:	
Professional organisation or society membership/affiliation:	Click here to enter text.
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	GMC 2593395

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?	25 years as Consultant Interventional Cardiologist in NHS. Prior experience of mitral-TEER. Currently CMO of Biosensors International who are developing a caval stenting device for the treatment of severe TR.
	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?	Rarely
	– 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	Yes

	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). Y I have done clinical research on this procedure involving patients or healthy volunteers. Y I have published this research. I have had no involvement in research on this procedure. Other (please comment)
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):	Title is confusing. Tricuspid edge to edge repair and caval stenting are different procedures to treat severe TR. Tricvalve is the brand name for a commercially available bi-caval stenting device. 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. Y The first in a new class of procedure. Y
4	Does this procedure/technology have the potential to replace current standard care or	Additional to medical therapy

	would it be used as an addition 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 substantially since publication of the guidance?	There are at least two edge to edge repair devices available and several caval stenting devices in development No prior guidance.

Current management

6	Please describe the current standard of care that is used in the NHS.	Medical therapy; rarely surgery
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?	Transcatheter tricuspid valve replacement – several devices available

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?	Improved QOL
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Severe CHF with severe TR
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 Yes
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Cath lab space, trained operators
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, extensive

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:	Procedural complications

	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?	Mortality, hospitalisation, QOL
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Many. Sham/placebo controlled studies are essential
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes
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. Fewer than 10 specialist centres in the UK. Y 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.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yes
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)?	
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	Beneficial outcome measures: Adverse outcome measures:

	procedure timescales over which these should be measured:	

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.	Chief Medical Officer Biosensors International	**2020**	**ongoing**
Choose an item.			
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:	**Keith G Oldroyd**
Dated:	**28/11/2027**

View results

Respondent

42 Anonymous

70:13
Time to complete

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

Bicaval valve implantation for tricuspid regurgitation (IP2009)

Your information

2. Name: *

Dr Rajiv Das

3. Job title: *

Consultant Interventional Cardiologist

4. Organisation: *

Freeman Hospital, Newcastle Upon Tyne

5. Email address: *

6. Professional organisation or society membership/affiliation: *

British Cardiovascular Intervention Society

7. Nominated/ratified by (if applicable):

British Cardiac Intervention Society

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

GMC 4516899

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?

Yes I am familiar with this technology. I have performed 4 Bicaval Valve Implantations for Tricuspid Regurgitation and Caval reflux in the last 12 months.

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.

This technology has only been used in once centre in the UK, the Freeman Hospital, Newcastle Upon Tyne. I am the only cardiologist in the UK performing this procedure. There is a significant number of patients who may be eligible for this technology. These are patients with heart failure secondary to severe tricuspid regurgitation resistant to medical therapy. Currently this is an unmet need for patients with severe symptomatic heart failure with severe tricuspid regurgitation and caval reflux. These patients are treated with GDMT and continue to be severely symptomatic.

The technology is only used by interventional cardiologists.

Patients will be evaluated in a local heart team MDT (attended by imaging specialists, heart failure consultants, cardiac surgeons and structural interventional cardiologists). The assessment for this procedure involves a comprehensive assessment by a heart failure cardiologist, interventional cardiologist and consultant with an interest in echocardiography.

12. 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

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?

There is currently an unmet need to treat patients with tricuspid regurgitation who are deemed high risk for surgical open heart repair. These patients are frequently hospitalised with heart failure and have significant morbidity and mortality associated with the condition if left untreated.

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?

These patients are treated with GDMT and continue to be severely symptomatic. It would be used in addition to existing standard care to improve QoL, frequent hospital admissions and morbidity.

Current management

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

Heart failure medication such as diuretics

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?

There is no established procedure for severe TR and caval reflux. The transcatheter edge to edge repair (TEER) technology has been established in some European centres for severe TR but the tricuspid valve is complex and not all patients are candidates for TEER due to a large coaptation gap, complex anatomy and presence of pre-existing pacing leads.

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?

Left untreated, patients with severe TR face a dismal prognosis. Current therapies focus on edge-to-edge repair or orthoptic replacement strategies. Not all patients are suitable for these therapies due to complex anatomy, large coaptation gaps and expertise. Heterotropic bicaval stenting, or caval implantation (CAVI), has emerged as a possible transcatheter strategy for indirectly treating the systemic effects of severe TR. This approach carries the inherent advantages of a streamlined fluoroscopic procedural workflow using familiar concepts akin to transcatheter aortic valve implantation.

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

• Adults with severe symptomatic severe TR (grade 3+ or more in a 5-grade classification)
• with symptomatic heart failure despite guideline derived medical therapy (NYHA functional class III or IV)
• echocardiography demonstrating significant backflow in the IVC and/or SVC, with a v wave ≥ 25mmHg as demonstrated by right heart catheterisation
• Left ventricular ejection fraction ≥ 40% and need to be able to reach a 6-minute walk distance of ≥60m
• deemed high risk to undergo conventional open surgical repair/replacement and/or may be considered for this treatment on compassionate grounds
• Evaluated by clinical and local heart team

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?

The technology could lead to fewer hospitalizations with heart failure and improve symptoms and quality of life.

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

None. This approach carries the inherent advantages of a streamlined fluoroscopic procedural workflow using familiar concepts akin to transcatheter aortic valve implantation.

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

As this procedure uses the same clinical skills set required for transcatheter aortic valve implantation it can be adopted easily into existing practice within TAVI centres.

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

In the TRICUS Euro study procedural success was reported at 94% with no procedural deaths or conversion to surgery. There was 1 device embolization noted in the study of 35 patients. 1 patient required a new permanent pacemaker. There was no device-related mortality observed and 3 patients (8.5%) had died at 6 month follow up. None of the deaths was recorded as cardiovascular in nature (subdural haematoma, kidney and respiratory failure in a patient with prior severe lung and kidney disease, and pneumonia). No cases of MI, cardiac tamponade, or cardiac surgery for failed device implantation were recorded up to 6-month follow-up. 2 cases of major bleeding were related to access site complications

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

Improvement in QoL
Improvement in 6 minute walk test
Hospitalisation with heart failure

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

This procedure is only suited with patients with severe TR and caval reflux.
Patients should be excluded from this technology of they have severe pulmonary hypertension and RV function.
Patients who are not able to take anticoagulation would also not be suitable for this procedure.

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

No. There is European Registry data and a global RCT (TRICAV study) is about to commence

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.

    (1) Estevex-Loureiro R et al. 6-month Outcomes of the TricValve system in patients with Tricuspid Regurgitation J Am Coll Cardiol Intv 2022;15:1366-1377)
    (2) Alexander Lauten, Hans R. Figulla, Christoph Willich, Christian Jung, Wilma Rademacher, Harald Schubert, Markus Ferrari,
    Heterotopic Valve Replacement as an Interventional Approach to Tricuspid Regurgitation,
    Journal of the American College of Cardiology,
    Volume 55, Issue 5,
    2010,Pages 499-500,ISSN 0735-1097,https://doi.org/10.1016/j.jacc.2009.09.034.
    (3) Interventional Treatment of Severe Tricuspid Regurgitation
    Early Clinical Experience in a Multicenter, Observational, First-in-Man Study
    Alexander Lauten, Hans R. Figulla, Axel Unbehaun, Neil Fam, Joachim Schofer, Torsten Doenst, Joerg Hausleiter, Marcus Franz, Christian Jung, Henryk Dreger, David Leistner, Brunilda Alushi, Anja Stundl, Ulf Landmesser, Volkmar Falk, Karl Stangl and Michael LauleOriginally published14 Feb 2018https://doi.org/10.1161/CIRCINTERVENTIONS.117.006061Circulation: Cardiovascular Interventions. 2018;11:e00606

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

    TRICAV Pivotal Trial Dr Samir Kapadia, MD and Dr. Rishi Puri, MD, PhD, FRACP, the Co-PI's of the Clinical Trial, Cleveland Clinic Ohio

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

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)?

    12 patients per year per centre

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.

    Procedural success,
    QoL, NYHA Class, 6 minute walk death, Hospitalisation with Heart Failure

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:

    valve embolisation, vascular complication, need of renal replacement therapy, LOS, Death, Significant bleeding

Further comments

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

This device should be used in centres competent at performing transcatheter aortic valve implantation.
Expertise from imaging and heart failure consultants is required to screen suitable patients

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. *

I have no interests to declare.

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: *

Rajiv Das

41. Date: *

09/10/2023

View results

Respondent

39 Anonymous

26:22
Time to complete

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

IP2009

Your information

2. Name: *

Dr Robert Smith

3. Job title: *

Consultant Cardiologist

4. Organisation: *

The Royal Brompton & Harefield Hospitals NHS Foundation Trust

5. Email address: *

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

Dr Andrew Ludman

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

4629768

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?

I am familiar with the procedure and the technology. I have not personally performed the procedure which has been undertaken less than ten times in the UK to my knowledge. I am, however, very familiar with the current devices. I am a recognised expert on the tricuspid valve and transcatheter tricuspid therapies.

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.

No

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 innovative compared to other techniques. The therapy is based on earlier experience with different bicaval valve placements

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?

Addition to standard care for very selected patients

Current management

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

The standard of care is currently either surgical intervention, transcatheter edge to edge repair (TEER) or medical therapy. Which therapy will depend on the patient's level of risk

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?

    Symptomatic benefit in selected circumstances where other techniques are not feasible

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

    As above. High risk patients who remain symptomatic and in whom surgery, TEER and TTVR (novel and emerging transcatheter replacement therapies) are not an option

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?

    It may, although more data would be needed

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

    None specifically

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

    Yes. Although I do not anticipate it to be too challenging

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

    This is a low risk intervention to my knowledge. As with any such procedure, the risks are predominantly related to cardiac and vascular trauma. This is similar for multiple similar procedures. The risk of cardiac tamponade is likely to be around 1% and major bleeding up to 5% (as seen with most tricuspid valve therapies)

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

Symptom improvement, KCQQ improvement, reduction in heart failure hospitalisation, (mortality benefit)

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

I do have some uncertainty about the long term benefits of this procedure which some consider to be a near palliative intervention in very symptomatic individuals. The 'ventricularising' of the right atrium has previously been associated with poor outcomes in small group experience with the Sapien prostheses

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

Yes - this is largely an unproven technique

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.

Multicenter Study JACC Cardiovasc Interv
. 2022 Jul 11;15(13):1366-1377. doi: 10.1016/j.jcin.2022.05.022. Epub 2022 May 17.
6-Month Outcomes of the TricValve System in Patients With Tricuspid Regurgitation: The TRICUS EURO Study

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

Not to my knowledge

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

Laule M., Mattig I., Schobel C. Inferior caval valve implantation versus optimal medical therapy for severe tricuspid regurgitation. J Am Coll Cardiol. 2019;74:473–475

This is with the now largely unused SAPIEN bicaval implant technique but is a similar concept

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)?

Less than 100 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.

Improvement in KCQQ, reduction in hospitalisation

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:

30/7 or 6 month death, cardiac tamponade

Further comments

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

I firmly believe that we need more research with this technique. I am not aware of large studies demonstrating benefit over medical therpay

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. *

none

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: *

    Robert Smith

41. Date: *

    04/10/2023

View results

Respondent

6 Anonymous

11:16
Time to complete

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

IP2009 Tricvalve Bi-caval valve implantation for Edge 2 Edge repair

Your information

2. Name: *

Sam Dawkins

3. Job title: *

Consultant Cardiologist

4. Organisation: *

John Radcliffe Hospital, Oxford

5. Email address: *

6. Professional organisation or society membership/affiliation: *

BCS, BCIS

7. Nominated/ratified by (if applicable):

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

6143008

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?

Yes

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.

No - I am aware of the design and have seen some cases performed at conferences. I am also familiar with the research in the area.

12. 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

13. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) No - it is not an edge-to-edge repair device, it is a replacement device.

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?

The standard of care for this group of high risk patients is generally medical management (i.e. medication only, no procedure or surgery). Few patients are offered edge-to-edge repair because of limited availability in the UK and some valve anatomy is not suitable for it. This would provide a relatively low-risk treatment option for patients with refractory right sided heart failure.

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?

Addition - this procedure would be used for patients who are not currently being offered any treatment.

Current management

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

Medical management (i.e. tablets only) - so offering interventional treatment to this group of patients is definitely an unmet need.

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?

Tricuspid edge-to-edge repair: this is a good option but not suitable for everyone and not widely available.
Transcatheter tricuspid valve replacement: not yet available in the UK but likely to be an option in the near future.
Tricuspid valve surgery: tiny numbers done in the UK. Surgical risk is high.

This technology would be a useful addition to the armamentarium we have available to treat tricuspid regurgitation and would provide an option for patients with no other options who generally do badly and have frequent hospital admissions.

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?

More highly symptomatic patients could be treated

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

Those unsuitable for the other technologies

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 - I suspect it could lead to reduced hospital admissions for these patients

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

No real changes needed - existing infrastructure is suitable for using this technology

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

Yes - the manufacturer would provide training. Existing Mitral/Tricuspid Heart Team meetings are well set up to screen patients for this technology

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

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

Procedural: Death, stroke, emergency surgery, survival to hospital discharge
Longer-term: Rehospitalisation, symptom improvement (e.g. change in KCCQ score), death

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

Few patients have been treated so far but early data is promising. This appears to be a relatively low-risk proceudre and much lower risk than surgery.

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

Not that I am aware of

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.

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

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)?

Difficult to be sure. Perhaps 30 in the first year nationwide

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.

Outcomes as listed earlier

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:

Outcomes as listed earlier

Further comments

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

N/A

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. *

N/A

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: *

    Sam Dawkins

41. Date: *

    31/05/2023