View results

Respondent

133 Anonymous

17:14
Time to complete

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

IP2039 Hildick-Smith

Your information

2. Name: *

David Hildick-Smith

3. Job title: *

Consultant Cardiologist

4. Organisation: *

University Hospitals Sussex

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BCIS, BCS, EAPCI, ESC

7. Nominated/ratified by (if applicable):

NICE

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

3337691

9. I confirm that:

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

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

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

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

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

Yes

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

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

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

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

Yes

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

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

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) No
- ( ) Other

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

Yes

16. Does this have a multi-indication?

Que?

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

Novel

18. Which of the following best describes the procedure:

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

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

Addition

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

Yes, iterating rapidly

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

- (●) Yes
- ( ) No

Current management

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

Diuretics

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

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

Tricuspid clip therapy (unfunded)

Potential patient benefits and impact on the health system

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

Relief of breathlessness and swollen abdomen and legs

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

Just those with severe tricuspid regurgitation

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

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

Definitely, if successful

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

Hybrid or high-capacity cardiac catheter lab

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

Yes, lots

Safety and efficacy of the procedure/technology

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

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

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

Death 3%; Pacemaker implantation 20%; vascular injury 5%; right ventricular failure 5%

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

Relief of breathlessness, improvement in quality of life, reduction in diuretic use, reduction in hospitalisation episodes, better survival.

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

Developing apace....best devices and best practices are evolving.
Assessing outcomes without placebo bias very difficult!

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

Yes. There is medical community uncertainty about how much patients will benefit

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

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

Abstracts and ongoing studies

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

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

Nothing that would evade a standard search

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

VDyne trial; TARGET trial; TRISCEND 2; TANDEM 1

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

All on PubMed

Other considerations

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

About 100 per year in the UK

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

Beneficial outcome measures.

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

QOL; NYHA; Diuretic regime; 6 minute walk time; hospitalisations; pacemaker implantation, major bleeding, procedural mortality, mortality during follow-up

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

Adverse outcome measures.

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

in-hospital, 30-day, one year, three year, five year outcomes

Further comments

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

Lots of ongoing studies

Declarations of interests

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

41. Type of interest: *

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

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

No conflicts of interest specifically related to Tricuspid technologies. I have previously been paid by Edwards to give talks but the last time this happened was a couple of years ago.

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

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

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

David Hildick-Smith

45. Date: *

17/07/2025

View results

Respondent

123 Anonymous

28:41
Time to complete

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

Transcatheter tricuspid valve implantation for tricuspid regurgitation (IP2039)

Your information

2. Name: *

Jonathan Byrne

3. Job title: *

Consultant Cardiologist

4. Organisation: *

King's College Hospital

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BCIS

7. Nominated/ratified by (if applicable):

BCIS

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

4183161

9. I confirm that:

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

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

- (●) I agree
- ( ) I do not agree

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

I am familiar with the procedure/techmnolofy

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

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

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

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

I use this technology and and aware of hwo widelt it is used in the NHS. This is not a procedure which will be ised by clinicias in other specialties

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

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

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) No
- ( ) Other

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

Yes

16. Does this have a multi-indication?

No

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

This is very innoivative technology and represents a treatment option for patients which did not exist previously,.

18. Which of the following best describes the procedure:

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

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

This procedure ahs the portential to become the standard of care for many patients with severe tricuspid regurgitation who are not suitable candidates for conventional surgery

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

This is novel technology and the deivces being used are first generation

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

- (●) Yes
- ( ) No

Current management

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

Surgical tricuspid valve repair replacement for those who are suitable candidates
Medicl therapy (diuretics) for the vast majority

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

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

Percutaneous tricuspid valve repair (tricuspid TEER) is not reoutinely commissioned by the NHS but is an alternative technuque which can be offered to patients who are anatomically suitable for treatment

Potential patient benefits and impact on the health system

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

Improved quality of lide- recent studies have shown a dramatic improvement in QOL in the short term. Longer term follow uo is awaited

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

All groups of patients with severe TR whi are anatiomically suitable for the procedure have the potential to benefit

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

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

Yes- treatment has the potentiual to reduce hospitalisation for heart failure

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

Most tertiary centres have the capabilty to deliver this pricedure using exisitng facilities

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

Advanced imaging training- the procedure is dependent of expert 3 dimensional echocardiography
Operators will need specific device training

Safety and efficacy of the procedure/technology

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

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

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

10% rate of major bleeding post procedure, almost certainly related to anticaogulation requirements
4% vascular injury
25% rate of new pacemaker implantation

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

Inproved quality of life
Reduced hospitalisation for heart failure

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

Durability of the bioprosthesis. Current follow up of limited duration

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

Studies have yet to demonstrate a mortality benefit from the procedure

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

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

Abstracts and ongoing studies

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

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N Engl J Med 2025;392:115-126
DOI: 10.1056/NEJMoa2401918

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

Triscend 2 - ongoing

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

Other considerations

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

200-300 per year

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

Beneficial outcome measures.

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

Short term- procedural mortality/residual TR severity/baseline NHYA/
Medium term- NHYA class/QOL improvement/BNP
Long term- valve function/NHYA class/QOL

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

Adverse outcome measures.

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

Short term- procedural mortality/vascular complications/new pacemaker implantation
Medium term- mortality/hospiutalisation for heart failure/
lomg-term- Mortality/Structural valve dysfunction/reintervention rates

Further comments

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

more reseearch is needed on the long temr efficacy of TTVR and outcome data

Declarations of interests

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

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

Hav received payment for advisory board/proctoring fron Edward Lifescinces and Abbott Vascular - both companies which manufacture tricuspid valve replacement/repair devices

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

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

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Jonathan Byrne

45. Date: *

05/05/2025

View results

Respondent

135 Anonymous

33:37
Time to complete

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

IP2039

Your information

2. Name: *

Rajiv Das

3. Job title: *

Consultant Cardiologist

4. Organisation: *

Newcastle Hospitals NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

BCIS

7. Nominated/ratified by (if applicable):

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

4516899

9. I confirm that:

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

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

- (●) I agree
- ( ) I do not agree

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

Yes I have used this technology and implanted two tricuspid valve replacements

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

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

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

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

Currently using this technology. Approximately 40 implants have been performed in the UK.
Involves a multidisciplinary team of interventional cardiologists, imaging experts and cardiac surgeons.
Likely to be performed only in major tertiary cardiac centres.
Anticipate 10 implants per year per centre approx 300 cases per annum in UK

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

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

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) No
- ( ) Other

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

Yes

16. Does this have a multi-indication?

No

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

Adds to the current treatment options for tricuspid regurgitation in high risk patients. Other treatment option include T-TEER and caval valve implantation

18. Which of the following best describes the procedure:

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

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

Could replace current standard care

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

No

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

- (●) Yes
- ( ) No

Current management

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

Recurrent admissions with heart failure requiring prolonged hospitalization and diuretics

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

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

Caval valve implantation and TEER

Potential patient benefits and impact on the health system

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

Reduce hospitalisation with heart failure, improve symptoms and quality of life

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

Patients with heart failure caused by severe tricuspid regurgitation

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

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

Yes improved clinical outcomes and reduce hospitalisation

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

Transoesophagel echo, General anaesthetic and team working with interventional cardiology and imaging, heart failure specialists

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

Yes training required delivered by manufacturers

Safety and efficacy of the procedure/technology

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

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

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

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

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

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

Good RCT evidence

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

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

Abstracts and ongoing studies

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

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

TRISCEND studies

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

TRISCEND II

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

Other considerations

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

300

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

Beneficial outcome measures.

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

Heart failure admissions
NYHA class improvement
6 minute walk test
Kansas questionnaire

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

Adverse outcome measures.

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

Permanent pacemaker implantation rates post procedure
Major bleeding
Device embolisation
Paravalvular leak
Need for renal replacement therapy

Further comments

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

Patients with severe RV impairment and severe pulmonary hypertension no suitable
Caution in patients with significant left sided valve disease, severe LV impairment and significant renal impairment

Declarations of interests

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

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

No interests to declare

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

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

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Rajiv Das

45. Date: *

02/08/2025

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: Click here to enter text.**IP2039 Transcatheter tricuspid valve implantation for tricuspid regurgitation**

Your information

Name:	Click here to enter text.Patrick Calvert
Job title:	Click here to enter text. Consultant Cardiologist
Organisation:	Click here to enter text. Royal Papworth Hospital
Email address:	Click here to enter text. [redacted]
Professional organisation or society membership/affiliation:	Click here to enter text.BCIS, BCS, RCP
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text.4732149

How NICE will use this information:

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? 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	Familiar with technology. As a centre we have undertaken the training on the system and plan to commence the procedure in September 2025. Numbers are low and are captured in the BCIS TMTV database. I would estimate around 5 specialised cardiothoracic centres currently undertake the procedure. This is likely to increase at a fairly slow rate as many patients can been treated by tTEER. Patients enjoy significant symptom improvement as evidenced by TRISCEND-II study. Procedure is only performed by interventional cardiologist (my own specialty) with imaging guidance from consultant echocardiographer (TOE)

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	~~I have done bibliographic research on this procedure.~~ ~~I have done research on this procedure in laboratory settings (e.g. device-related research).~~ ~~I have done clinical research on this procedure involving patients or healthy volunteers.~~ ~~I have published this research.~~ I have had no involvement in research on this procedure. Other (please comment) I have undertaken a number of invited presentations at national meetings on this topics but am not currently directly involved in research on this topic
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. Does this have a multi-indication? 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 yes no this is a major advancement on current therapy providing anatomical correction of the valve leakage with clinical improvement as evidenced by the randomised control trial. This allpws patients who previously would not have received any treatment to have treatment and enjoy symptomatic benefit

		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. None of these adequately describe the procedure. It is established practise in a small number of highly specialised cardiothoracic centres. It has RCT proven 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?	Yes, however it is unlikely ever to be high volume
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 There was no prior guidance, and now there is good arc data

Current management

6	Please describe the current standard of care that is used in the NHS.	The current standard of care for these patients is supposed to be open cardiac surgery to repair the tricuspid valve. However in practise very very few patients receive this as they are

		usually turned down for treatment a surgical outcomes have previously been poor
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 edged edge repair of the tricuspid valve allows for treatment of the TR using a different technique.

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?	Complete and effective correction of TR and significant clinical improvement in symptoms
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients who have symptomatic severe tricuspid regurgitation (TR) who are note suitable for TEER and in whom RV function that is still relatively preserved
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 procedure is already leading to improved outcomes fewer hospital treatments less admissions and improved symptoms,
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	No changes are required, this procedure can be (and is) undertaken in existing specialised valves centres
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes specific training is required and is already available

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:	this procedure involves the passage of a large bore sheath through the right femoral vein and as such there is a risk of damage to this during the procedure. This procedure results in complete cessation of tricuspid valve leak and as such it's important that the right ventricle is no more than moderately impaired. There is also a risk of damage to the heart, pulmonary embolism and blood clot. The full list of adverse reactions and their incident as can be seen in the TRISCENCD-II paper

	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?	improvement in NYHA breathlessness classification, reduced admissions with heart failure
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	the data that exists already for this procedure is quite compelling with good outcomes. Like any procedure, more prolonged follow up is always desirable
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	no
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. 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	See above

	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.	TRISCEND-2
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)?	It is likely that this procedure will remain low volume for quite a long time. Once training has been undertaken, I would estimate that a maximum of 500 patients a year would benefit from this procedure but I would estimate it would probably take 10 years to get to this level in the UK
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: 1 NYHA classification 2. TR grade 3 heart failure admissions Adverse outcome measures: death, need for urgent surgery, vascular complications

	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.	

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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
Non-financial professional	Soon to be an implanter of the device	**June 2025**	
Indirect	Undertook a talk (on a different topic) at an education meeting with speaker fee from Edwards (manufacturer of a TTVR)	**11th July 2025**	**11th July 2025**
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:	**Click here to enter text. Patrick Calvert**
Dated:	**Click here to enter text. 30th July 2025**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP2039 Transcatheter Tricuspid Valve Replacement**

Your information

Name:	Adnan Nadir
Job title:	Consultant Cardiologist
Organisation:	University Hospital Birmingham
Email address:	[redacted]
Professional organisation or society membership/affiliation:	BCIS, ACC, ESC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	06048882

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?	As a structural interventional cardiologist, I am familiar and a regular user of Transcatheter Tricuspid Valve Replacement technology. It has long been an area known for lack of technological advancement. However, with rapid advancement in transcatheter technology many patients can now be potentially treated who traditionally were palliated before their time. At UHB, we are fortunate to be able to offer this novel technology to carefully selected patients. The procedure is predictable, safe and much lower risk than conventional surgery. Although we do not have long term outcome, this is an area where no good data exist for conventional options.
	Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the	At the moment due to lack of resources the use is limited but it is likely to expand as currently there is no good treatment options for isolated severe tricuspid valve disease.

	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, the procedure is either performed by interventional cardiologist alone or in conjunction with cardiac surgery. NA
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 published this research. 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):	Currently it is restricted to those with not suitable for transcatheter repair. This recommendation is not based on any good evidence and largely based on illogical comparison with conventional surgery which is a completely different approach which itself lack good quality RCT data. This is transformative technology with many parallels to that of TAVI The first in a new class of procedure.

4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	It will be used as an addition but has potential to replace as more data becomes available since existing standard of care is not really evidence-based.
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?	NA

Current management

6	Please describe the current standard of care that is used in the NHS.	Currently vast majority of these patients are either not referred or when referred are turned down for treatment as there is no good treatment option. Conventional surgery is only rarely performed for isolated TR and not many cardiac surgeons have large experience and outcomes are universally poorer than other valve surgeries.
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?	Tricuspid valve repair and Caval valve implant but they are not routinely funded or available in NHS either

	If so, how do these differ from the procedure/technology described in the briefing?	Tricuspid valve replacement is more definitive and predictable treatment while caval implant technology are more or less palliation.

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 quality of life, reduced hospitalisation and if performed in timely fashion potentially improved survival.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Those with high Tri-Risk Score with Isolated Tricuspid valve regurgitation
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, clear data supporting this assertion.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	This can be performed safely in established NHS cardiac surgical centres with structural program.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, but no challenging for those who regularly perform mitral and aortic procedures.

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:	Bleeding, leaflet thrombosis and need for pacemaker.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Improved NYHA class, improved KCCQ score, improved 6 min walk test, improved RV remodelling, reduced hospitalisation
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Cost and long-term data
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Current standard of care and surgery as 'gold standard' treatment is based on anecdotes and eminence-based evidence rather than good quality data. We don't fully understand what symptoms are attributable to TR for and timing for intervention.
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	Lu FL, An Z, Ma Y, et al. Transcatheter tricuspid valve replacement in patients with severe tricuspid regurgitation. *Heart* 2021;107:1664–70. Kodali S, Hahn RT, George I, et al. Transfemoral tricuspid valve replacement in patients with tricuspid regurgitation: TRISCEND Study 30-Day Results. *JACC Cardiovasc Intv* 2022;15:471–80. Buğan B, Çekirdekçi Eİ, Onar LÇ, Barçın C. Transcatheter tricuspid valve replacement for tricuspid regurgitation: a systematic review and meta-analysis. *Anatol J Cardiol* 2022;26:505–19. Hahn RT, George I, Kodali SK, et al. Early single-site experience with transcatheter tricuspid valve replacement. JACC Cardiovasc Imaging 2019;12:416–29.

	comprehensive reference list but it will help us if you list any that you think are particularly important.	Fam NP, von Bardeleben RS, Hensey M, et al. Transfemoral transcatheter tricuspid valve replacement with the EVOQUE system: a multicenter, observational, first-in-human experience. JACC Cardiovasc Intv 2021;14:501–11.
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Yes • TRISCEND II This randomized clinical trial (NCT04482062) is evaluating the safety and effectiveness of the EVOQUE valve, which is designed to replace the tricuspid valve without open heart surgery. The trial will enroll more than 700 patients with severe tricuspid regurgitation who are not candidates for other treatments. The trial's results could lead to new standards for future trials and expanded treatment options for patients. • TRAVEL This trial in China is investigating the LuX-valve, which is a self-expanding nitinol stent with an atrial disc, interventricular septal anchor, and two graspers. The LuX-valve is delivered using a transatrial approach. • TRAVEL II This trial in China is also investigating the LuX-valve, but using a transjugular approach. Other TTVR trials include early feasibility trials for Cardiovalve, Intrepid, and TricValve.
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 predict but currently only 5% of patients with severe symptomatic TR undergo cardiac surgery. I suspect only minority will be suitable for TTVR as well as technology stands.

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: Re-Hospitalisation, Quality of life measures. Most appropriate is PROM (Patient reported outcome measure) Adverse outcome measures: Bleeding, valve dysfunction.

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

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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:	**Dr Adnan Nadir**
Dated:	**03/07/2025**