View results

Respondent

78 Anonymous

68:24
Time to complete

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

IP2042 Surgical Insertion of a Catheter based intravascular microaxial blood pump

Your information

2. Name: *

Colin Chue

3. Job title: *

Consultant Cardiologist

4. Organisation: *

Queen Elizabeth Hospital Birmingham

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

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

6073234

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.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. Used in selected patients with cardiogenic shock as a bridge to definitive treatment (heart transplantation or durable left ventricular assist device)

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.

Have previously used and are still using.
This is a treatment that will likely be limited for use in advanced heart failure centres in the UK.
We implant this pump together with cardiac surgeons in cardiac surgery theatres. I do not see it being used outside of a cardiology/ cardiac surgery setting.
Our specialty is involved in patient selection. We have used this device as a short-term mechanical circulatory support bridging device to heart transplantation, both alone and alongside a percutaneous right ventricular assist device for biventricular support. Patients deemed suitable for this device have undergone assessment and agreed to be suitable for advanced heart failure therapies, including heart transplantation. Number implanted in our centre is around 5-10

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

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

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

Possible proposed indications: 1) Cardiogenic shock due to left ventricular failure as bridge to heart transplantation or durable left ventricular assist device; 2) Cardiogenic shock due to left ventricular failure as bridge to recovery (in conditions where left ventricular recovery is possible e.g. acute myocarditis); 3) Cardiogenic shock due to biventricular failure when used alongside a right ventricular assist device as bridge to heart transplantation

16. Does this have a multi-indication?

Yes (see above)

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- current standard would be an Impella CP. This pump requires surgical implantation via a graft on the axillary artery under general anaesthetic, compared to direct insertion into the femoral artery as per the Impella CP. This is usually performed in an operating (or hybrid) theatre environment, as opposed to the cardiac catheterisation laboratory. The pump provides a higher level of blood flow (up to 5.5l/min compared to 3.5l/min) for full left ventricular support.

18. Which of the following best describes the procedure:

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

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

Addition to existing standard of care.

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

Not as far as I am aware

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.

Other forms of short-term mechanical circulatory support, e.g. veno-arterial ECMO, Impella CP, surgical biventricular assist device

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?

As above:
VA ECMO- used in the short term for cardiogenic shock for full cardiopulmonary support. Requires conversion to a more durable form of short-term mechanical circulatory support (e.g. surgical biventricular assist device, Impella 5.5) to successfully bridge to heart transplantation
Impella CP- used alongside VA ECMO to "vent" the left ventricle. Also used for peri-procedural support in high risk cases e.g. PCI. Usually inadequate to provide full left ventricular support as a single device
Surgical biventricular assist device- requires surgical implantation via sternotomy. Provides full biventricular support as a bridge to definitive therapy e.g. heart transplantation

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?

Avoidance of sternotomy (surgical biventricular assist device). Can allow ambulation (use of axillary artery in the chest) whilst awaiting definitive therapy.

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

Appropriate selected patients with significant left ventricular dysfunction and cardiogenic shock to bridge them to definitive therapy e.g. heart transplantation, durable left ventricular assist device

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?

    Less invasive treatment- no need for sternotomy (in the case of surgical biventricular assist device), particularly if there is a chance of recovery of myocardial function

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

    Ideally inserted in a hybrid operating theatre with fluoroscopy. At present we have inserted this in a standard operating theatre with a portable C-arm for fluoroscopy, which is possible

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

    Initial training (via proctoring or a simulator) for insertion and appropriate placement would be beneficial

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

    In the literature:

    Haemolysis
    Infection
    Bleeding/ haematoma from vascular access site (3/14)
    Acute kidney injury (3/14)
    Device migration
    Thromboembolic events (stroke 1/14)
    Aortic valve injury (Ghannam AD et al, Cureus 2021; 13: e13235)
    Mitral valve regurgitation
    Device failure
    Death

    Kennel PJ et al. ESC Heart Fail 2021; 8: 3720-5.
    Debenham R et al. J Am Coll Cardiol 2022; 79: 487.

    We have seen access site haematomas and bleeding from our own experience.

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

    Successful bridging to i) recovery to device explant or ii) heart transplantation/ durable left ventricular assist device

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

    Still a relatively new device. Further clinical experience regarding efficacy and adverse events will be insightful.

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

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.

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

    J-PVAD- Japan Registry for Percutaneous Ventricular Assist Device

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)?

Approximately 5-10 in our centre. Extrapolating to other advanced heart failure centres in the UK, approximately 30-60

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.

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:

Early (days to weeks):

Haemolysis
Infection
Bleeding/ haematoma from vascular access site
Acute kidney injury
Device migration
Thromboembolic events
Aortic valve injury
Mitral valve regurgitation
Device failure
Death

Late (weeks):

Infection
Bleeding/ haematoma from vascular access site
Device migration
Thromboembolic events
Aortic valve injury
Mitral valve regurgitation
Device failure
Death

Further comments

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

No further comments

Declarations of interests

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

41. Type of interest: *

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

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

I have received honoraria from Abiomed for running courses in short-term mechanical circulatory support. Abiomed manufacture the Impella 5.5 micro-axial pump

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: *

    Colin Chue

45. Date: *

    08/05/2024

View results

Respondent

85 Anonymous

21:05
Time to complete

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

Impella

Your information

2. Name: *

smail hassiba

3. Job title: *

Transplant consultant surgeon

4. Organisation: *

Royal papworth hospital

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

International society of heart and lung transplant

7. Nominated/ratified by (if applicable):

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

7572023

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 in formation 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?

    Very familiar

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 have used it and I'm using it.
    Good device in some indications of heart failure as a transplant surgeon I make the indication as well

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

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

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

16. Does this have a multi-indication?

It's had an indication in bridge to transplant Or to durable mechanical support as well as to unload the left ventricle in case of ecmo

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

It's a novel approach as we used the impella 5 widely
The insertion is the same
The impella 5.5 had some technical improvements and less complications such as hemolysis and it's longer durability

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?

It's an addition

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.

The standard of care is ECMO/ BIVaD

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?

BIvAd is more invasive requiring sternotomy and the rehabilitation process is more difficult

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?

No redo surgery
Mobilisation
No bleeding no transfusion no sensitisation
Easy to bridge to transplant

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

Heart failure : chronic and acute
Bridge to recovery post cardiotomy
Bridge to transplant
Bridge to LVAD

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?

    Absolutely

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

    Hybrid theatre
    X rays during insertion

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

    Yes .
    Theoretically and technically
    Require training on mannequin or cadavers

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

    Stroke
    Bleeding
    Infection
    Hemolysis
    Aortic/ mitral valve damage

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

    Easy insertion
    Less invasive

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

    Duration of use

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

    Duration of use

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

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

Abstracts and ongoing studies

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

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

    ISHLT abstracts 2024

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

    Danger (impella CP)

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)?

30 a 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.

Symptoms improvement:
Heart failure clinical and metabolic symptoms
Kidney and liver function
Lung function
Mobility
Eligibility for transplant post insertion
Unloading of the ventricle
Hémodynamique measurement

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:

Stroke
Infection
Bleeding
Hemolysis
Arrhythmia
Valve damage

Further comments

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

Duration of use with safety

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 interest

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: *

smail hassiba

45. Date: *

22/05/2024

View results

Respondent

81 Anonymous

19:23
Time to complete

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

IP2042 Surgical insertion of catheter based intravascular microaxial pump

Your information

2. Name: *

Mostafa ElAdawy

3. Job title: *

Consultant in Cardiothoracic anaesthesia and intensive care

4. Organisation: *

Newcastle upon Tyne hospitals

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

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

7189047

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 in formation 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 technology and the device, I had a training on the device from the company, I am using the device in my ICU and theatres

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.

It is only limited to some cardiac centres in the UK
It is used by cardiac surgeons and cardiologists as well as cardiac anaesthetists and intensivisits

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

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

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

I don;t know the proposed indication

16. Does this have a multi-indication?

yes

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 approach and concept

18. Which of the following best describes the procedure:

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

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

addition to existing standard care

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

yes, new devices and new concepts emerging in the market

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.

supportive management for cardiogenic shock, possibly escalating to ECMO for life threatening cardiogenic shock

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?

ECMO is another procedure, different device, different concept and different approach

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?

life saving, extend the time awaiting for heart transplant, safer procedure in high risk patients, amongst other indications...

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

cardiogenic shock

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?

    it can lead to improved outcome, but not necessarily fewer hospital visits or less invasive treatment

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

    well equipped cath labs, well trained staff in ICU, theatres and cardiology wards

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

    yes training is required on many levels, cardiologists, surgeons, intensivists, anaesthetists, nursing staff

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

    Aortic valve injury Bleeding Stroke Haemolysis
    Limb ischemia Thrombocytopenia Vascular injury Renal dysfunction

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

high risk PCI safely, recovery from cardiogenic shock, bridge to heart transplant, bridge to decision, bridge to durable device

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

it is still in the early days, robust data is not available yet, however, a recent trial DanGer trial has shown good survival rate compared to standard approach

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

N/A

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.

    DanGer trial,

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

    not aware

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)?

    hundreds to few thousands

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.

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:

Further comments

40. 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.

41. Type of interest: *

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

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

I attended a course on Impella sponsored by the company

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: *

Mostafa Eladawy

45. Date: *

14/05/2024

View results

Respondent

80 Anonymous

1304:58
Time to complete

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

IP2042 Surgical Insertion of a Catheter based intravascular microaxial blood pump

Your information

2. Name: *

Paul Callan

3. Job title: *

Consultant Cardiologist

4. Organisation: *

Manchester Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC

7. Nominated/ratified by (if applicable):

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

6104132

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 in formation 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?

No direct use, we are in the process of introducing the Impella 5.5 pump at our service, to support post cardiotomy shock, acute cardiogenic shock, and advanced heart failure patients. I have attended a recent intensive 2 day course to learn about indications, patient management whilst on support, weaning strategies and managing complications.

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.

We are not currently using the device in Manchester. I'm not aware that other centres are using in the UK currently. Across Europe there has been widespread usage. I would anticipate most UK transplant centres would begin to utilise this technology over the next 2- 4 years.

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

- [ ] I have done bibliographic research on this procedure.
- [ ] I have done research on this procedure in laboratory settings (e.g. device-related research).
- [ ] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [x] I have appraised the available registry and case series data on theuse of surgically implan

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

No indication in title

16. Does this have a multi-indication?

The indications are in the management of acute cardiogenic shock, post cardiotomy shock, and in end stage decompensated heart failure as a bridge to cardiac transplantation or durable mechanical circulatory support..

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 a novel device in terms of implantation technique, and level of haemodynamic support provided. It is a further advancement of short term microaxial pump technology, which were hitherto limited by the levels of flow that they could provide, and the complication rates related to device 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?

It has the potential to play an important role in the management of cardiogenic shock and post cardiotomy shock. Current mechanical support strategies include
1. Intra aortic balloon pump which provides a very small increase in cardiac output, and is insufficient in the majority of patients
2. Percutaenous micro axial pumps, again limited by the level of support they can offer.
3. Veno-arterial ECMO - high complication rates, only indicated for very short term use, do not decompress LV (unless used in conjunction with an another device such as an Impella)
4. Short term ventricular assist devices e.g centrimag - open procedure requiring sternotomy. Delays recovery, exposes to significant complications.

This technology can potentially provide levels of cardiac support similar to a short term VAD, without the need for a sternotomy and its attendant risks. We would also anticipate a faster post procedure recovery and early rehabilitation, facilitating earlier assessment of recovery potential/ need for long term VAD or transplant.

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

Evolution from Impella 5.0 to Impella 5.5 - shorter motor, no pigtail, allow for longer duration of support. This will be helpful for patients in whom venricular recovery takes more than a few days. It also allows it to be a bridging tool for cardiac transplantation.

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.

Current strategies for treating cardiogenic shock include

1. Inotropes/ vasopressors - short term augmentation in cardiac output- increase myocardial oxygen demand and predispose to arrhythmias. Neutral effects/associated with harm in most randomised studies.
2. Intra aortic balloon pump which provides a very small increase in cardiac output, and is insufficient in the majority of patients. Randomised data in acute MI shows no benefit.
3. Percutaenous micro axial pumps, again limited by the level of support they can offer. High complication rates, frequently related to femoral artery placement.
4. Veno-arterial ECMO - high complication rates, only indicated for very short term use, do not decompress LV (unless used in conjunction with an another device such as an Impella)
5. Short term ventricular assist devices e.g centrimag - open procedure requiring sternotomy. Delays recovery, exposes to significant complications.

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

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

    No

Potential patient benefits and impact on the health system

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

    There is currently a gap in our arsenal of treatments to manage cardiogenic shock. This has the potential to treat a significant number of patients who require more support than a balloon pump/ percutaneous microaxial flow device can provide, without exposing them to the risks associated with ECMO / short term VAD support.

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

    Patients with acute decompensated heart failure who fail to adequately respond to inotropes, and requiring optimisation to safely bridge to cardiac transplantation.
    Patients undergoing mitral valve surgery with pre-existing LV dysfunction
    Acute cardiogenic shock patients with predominant LV dysfunction in order to stabilise, wean off inotropes, and give conditions that would best facilitate myocardial recovery.

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?

    Data from Germany suggest that cardiogenic shock survival can be significantly improved with the use of surgically implanted microaxial flow pumps, as part of a comprehensive cardiogenic shock service. Recovery is much faster as compared to ECMO alone or surgically implanted VAD systems, thus potentially reducing ITU bed days.

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

    We will need access to fluoroscopy for device insertion in theatre. Alternative will be to perform procedures in a hybrid interventional radiology lab or cardiac catheter lab.

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

    Training sessions have already been arranged for critical care and surgical staff. The key issues will be recognising and managing complications, as well as guidance on device weaning.

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

    Complication rates 10 -20 % - lower with increasing experience (as with most procedures)
    Major bleeding
    Vascular complications
    Haemolysis
    Device migration requiring repositioning
    Stroke/peripheral emboli

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

    Survival to discharge
    Proportion weaned from support
    Time from intervention to transplant listing/ durable MCS
    Change in vasoactive inotrope score before intervention and 24 hours post

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

    Used extensively in mainland Europe, efficacy and complication rates established. Ongoing clinical trials examining their use following complex valve surgery/ post cardiotomy shock.

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

    Uncertainty regarding use in non transplant/ MCS cardiothoracic units. Will outcomes and complication rates be similar outside higher volume centres?.

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.

    Cardiogenic shock working group report on clinical outcomes in Impella 5.0, 5.5 recipients- presented at ISHLT 2024

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

    IMPACT trial - Impella protected cardiac surgery trial

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

    none

Other considerations

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

Across UK- approx 50 acute cardiogenic shock, 50 -100 support following complex valve surgery, 25-50 acute decompensated heart failure

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.

Survival to ITU discharge, hospital discharge 3 months and 1 year
Rates of complications - major haemorrhage, vascular complications requiring surgical intervention, rates of device failure, haemolysis rates
Impact of support on ITU length of stay, time to transplant/ durable MCS
Average time on support
Pain assessments vs short term VAD implantation
Time to first mobilisation vs short term VADS/ ECMO
Blood product usage vs VADs/ ECMO

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:

Major haemorrhage
Vascular complications
Rates of limb loss/amputation
Stroke rates
Haemolysis

Further comments

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

It is important that NHSBT mechanical circulatory support annual reports measure outcomes separately to compare with existing short term mechanical circulatory support methods.

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. *

None

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

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

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Paul Callan

45. Date: *

14/05/2024

View results

Respondent

82 Anonymous

38:58
Time to complete

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

IP2042 Surgical Insertion of a Catheter based intravascular microaxial blood pump

Your information

2. Name: *

Prof Stephan Schueler

3. Job title: *

Consultant Cardiac and MCS/Transplant Surgeon

4. Organisation: *

Newcastle upon Tyne Hospitals Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

GMC, FRCS, SCTS, AATS ISHLT, ISMCS, BSH

7. Nominated/ratified by (if applicable):

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

6032444

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 in formation 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 the surgical lead for this technology within our hospital, and it has become an integral in recent years. I am part of the MDT group which includes cardiologist and anaesthetists, perfusionists and specialized nurses.

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 am a regular user of this technology

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
- ( ) Other

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

yes

16. Does this have a multi-indication?

yes, this technology in its various forms can be applied in various clinical scenarios where patients hare in a state of severe acute of chronic heart failure

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

It offers a completely new approach in the treatment severe cardiogenic failure

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?

yes, can/ will replace the Intra Aortic Balloon Pump

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

the implantation technique has slightly changed but is basically the same

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.

there is no comparable technique established, and the present standard is the use of ECMO, drugs or the IABP

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?

ECMO, IABP,

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?

More effective in the treatment of cardiogenic shock/ failure, less invasive, allows better rehab of the patient on ITU, more versatile easy to implant and remove

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

acute cardiogenic shock, patients with chronic heart failure awaiting more durable treatment, is used as platform for high risk cardiac surgical procedures

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?

    it already has changed the approach in acute PCI based on recent clinical trials and surgical data published are supporting the application in the surgical setting in the same way.

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

    Needs a trained surgical team, anaesthetists, perfusionists, specialized nursed. This facilities are established in specialized centres already

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

    the application of this technology needs special training of everyone involved

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

    A detailed list of potential risks and adverse events are best summarized in the following publication from 2023

    Single center experience and early outcomes of Impella 5.5
    Masaki Funamoto, Chandra Kunavarapu, Michael D. Kwan2, Yuichi Matsuzaki1, Mahek Shah2 and Masahiro Ono1
    Frontiers in Cardiovascular Medicine, 02,2023

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

    see above

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

    patient selection will be crucial, and in the UK this learning curve is to be expected

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

    no

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 above the comprehensive literature search NICE will carry out anyway

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

    the important DanGER trial has just been published

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)?

more than 100 patients

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.

rescue success of cardiogenic shock, longer term myocardial recovery, successful bridge to heart transplantation, in case of myocardial recovery a significant improvement of QoL is expected.

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:

Complications related to the surgical implantation procedure, clotting problems, malposition, failure of the device needing replacement

Further comments

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

it has become an important tool in the treatment of advanced heart failure scenarios whether it is acute or chronic.

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. *

I am the lead of the MCS program in our unit, and therefore it is important for us to use this new technology as an adjunct to others already established since it will allow a significant improvement of the overall outcomes of these seriously ill group of patients

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: *

    Stephan Schueler

45. Date: *

    16/05/2024

View results

Respondent

84 Anonymous

57:26
Time to complete

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

IP2042 Surgical Insertion of a Catheter based intravascular microaxial blood pump

Your information

2. Name: *

Sai Bhagra

3. Job title: *

Consultant Cardiologist

4. Organisation: *

Royal Papworth Hospital

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

British Society for heart failure; International Society for Heart and Lung Transplantation

7. Nominated/ratified by (if applicable):

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

6058086

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 in formation 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 work as a cardiologist with patients with advanced heart failure and am very familiar with the use of temporary mechanical circulatory support devices in my daily practice. We have limited experience with the catheter based micro axial blood pump but this pump has a definite role in managing patients with cardiogenic shock.

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.

In the NHS this is being used for high risk PCI , high risk VT ablation and supporting patients with cardiogenic shock. My experience is with its use in patients in cardiogenic shock and it has a role in helping support patients with isolated left heart failure without the requirement for more invasive open heart procedure.

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

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

14. Does the title adequately reflect the procedure?

- (•) Yes
- ( ) Other

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

The indication for the IMpella 5.5 would be for SCAI C or worse cardiogenic shock in patients as BTR, BTD or BTT

16. Does this have a multi-indication?

It may translate in use for unloading LV in patients supported on VA ECMO.It may also become a pump utilised when weaning patients with poor LV function from bypass. THe Impella CP is used for supporting high risk PCI or VT ablation.

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

The 5.5 is a refined pump with the ability to provide full left heart support with a anecdotal reduction in the complications associated with the previous Impella devices such as hemolysis and renal injury. However there are no large trials described with this particular device (Impella 5.5) to support the observational data.

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?

The Impella 5.5 has the potential to replace VA ECMO in patients with cardiogenic shock requiring isolated left heart support. It also has the potential to be the LV unloading device of choice in patients supported on peripheral VA ECMO with LV distention with a view to then transitioning to Impella 5.5 and removing VA ECMO support in patients requiring longer periods of support.

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

The Impella family of devices has undergone upgrades from the CP onwards with the 5.5 the most recent iteration. There are observational studies describing greater cardiac support with fewer complications with the Impella 5.5.

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.

Patients with cardiogenic shock are managed pharmacologically with inotropes. Those unstable on inotropes who may be candidates suitable for cardiac transplant are then transitioned to temporary mechanical circulatory support either as a bridge to recovery, bridge to decision or bridge to transplant. Current temporary MCS is either VA ECMO (limited evidence of benefit in CS, duration of support measured in days) or more invasive (open heart surgery) implantation of CentriMAg pumps to support either the left heart, right heart or both.

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

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

No

Potential patient benefits and impact on the health system

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

Avoid open heart surgery for patients requiring temporary LV support and allow these patients to become ambulant more rapidly. Those who require cardiac transplant then are also lower risk as they would have avoided a sternotomy prior to transplant.

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

Patients with cardiogenic shock with isolated LV failure who are being bridged to transplant.

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?

Less invasive treatment for those in cardiogenic shock. Better outcomes reported in RCT using the Impella CP in patients with CS unlike neutral trials in those supported with VA ECMO.

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

This will need the increase in number of cardiologists, intensivists, cardiac surgeons familiar with its use and managing patients supported on this pump. This will require education and training. However if limited to advanced HF centers or a spook or hub model adopted then limited additional training would be required.

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

The team using the device will require training in its use and management

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

    Adverse events include hemolysis, vascular injury, bleeding, AKI, arrhythmia, site infection, migration of the pump, cardiac perforation, valve injury, thrombocytopenia, anemia, stroke, embolisation, etc.

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

    Recovery and weaning from device to oral medical therapy
    Successful bridge to cardiac transplant
    Successful bridge to durable MCS such as LVAD
    Reduced rates of limb ischemia, bleeding, hemolysis c/w VA ECMO which is currently the most widely used temporary MCS device alternative for rapidly deployment in patients with cardiogenic shock.

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

    There is no RCT demonstrating survival advantage in patients with cardiogenic shock with the Impella 5.5. The DAnGer Shock was with the Cp device and this pump is associated with significant adverse effects such as bleeding, hemolysis and rates of patients needing renal replacement therapy.

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

    No - however the supportive data is observational and there is no RCT with this device.

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.

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

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)?

There are around 24000 pPPI – 10% rate of CS – 2400 patients and around 62000 patients admitted for acute heart failure with 5.8% mortality in < 75. However ~ 200 heart transplants performed per year in the UK. Therefore needs to be carefully introduced with strict indication criteria as transplantation will not be an option for the vast majority.

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.

Efficacy - Survival - recovery or after transplant @ 90 days and 1 year
Safety - Rates of RRT, hemolysis, infection, etc
Patients QoI At 90 days and 1 year.

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:

Main adverse events that should be measure include bleeding requiring transfusion, site infection, hemolysis, requirement for RRT, Days on ICU, limb ischmia, stroke, other embolic phenomenon

Further comments

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

The key would be to have defined population where its use is indicated knowing that cardiac transplantation is unlikely to be an option for the vast majority of patients who may benefit from this device but may not wean from it. It would be important to minimise situations where patients with absolute contraindications to cardiac transplant end up unweanable from this device.

Its use should be limited to units that are capable of managing the device and its complications and units who are capable of recognising absolute contraindications to transplantation and futility.

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
- [x] Indirect
- [ ] No interests to declare

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

I have attended meetings hosted by Abbott (Heart Mate3 LVAD) but have received no payments from any drug or device company.

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: *

Sai Kiran Bhagra

45. Date: *

18/05/2024

View results

Respondent

77 Anonymous

19:02
Time to complete

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

IP2042 Surgical Insertion of a Catheter based intravascular microaxial blood pump

Your information

2. Name: *

Stephen Pettit

3. Job title: *

Consultant Cardiologist

4. Organisation: *

Royal Papworth Hospital

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

Royal Papworth Hospital

7. Nominated/ratified by (if applicable):

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

6052477

9. I confirm that:

· I am a registered practising professional in the UK/NHS and in good professional standing

· I have specialist knowledge in the technology or disease area

· I will declare all conflicts of interest in relation to the technology under consideration

· I will abide by NICE's governance policies and comply with NICE's processes and methods

· I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

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

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

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

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

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

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

    Are you familiar with the procedure/technology?

I am familiar with the Impella 2.5, CP, 5 and now the 5.5. Our unit has used all these pumps as a bridge to heart transplantation

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.

The Impella CP and 5.0 has been used in the six UK advanced heart failure centres. All centres will move over to using the 5.5, now that this pump has replaced the 5.0. The 5.0 and 5.5 are used for mechanical circulatory support as a bridge to heart transplantation. The Impella CP is used more widely in the UK for procedural haemodynamic support (high risk PCI, catheter ablation of VT) and for emergency support of cardiogenic shock after myocardial infarction.

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

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

14. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) It describes the technique but not the indication or intended patient group

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

There is no indication in the title.

16. Does this have a multi-indication?

Yes

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

Minor variation on established design (Impella 5.0)

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?

It will replace the use of Impella 5.0 because this is being removed from the market.

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.

In patients who are potential candidates for heart transplantation but are likely to die before receiving a suitable donor heart, a range of blood pumps may be used to provide mechanical circulatory support as a bridge to heart transplantation. The most appropriate pump depends on the patient, pathology and clinical context. The Impella 5.5 is one such blood pump.

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?

Not at the moment. There was a competing product called the Abbott percutaneous heart pump but it failed in early development. There are similar microaxial percutaneous LVADs that are manufactured by Chinese MCS companies but these are not currently available in the UK.

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?

Survival

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

Advanced heart failure

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?

    It may reduce mortality on the heart transplant waiting list if it provides more effective or safer mechanical circulatory support that alternate blood pumps.

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

    None

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

    Yes

Safety and efficacy of the procedure/technology

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

    Numerous - these are detailed in large publications that have examined the FDA Maude database.

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

Survival to discharge.

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

I do not think the Impella 5.5 has been examined in a randomised controlled trial, so there are huge uncertainties about safety and efficacy. This is not unusual for MCS devices.

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

Not really.

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

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

Abstracts and ongoing studies

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

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

    https://www.jhltonline.org/article/S1053-2498(23)00032-3/fulltext

    This is interesting but the site of arterial access described in table 1 raises questions about the Impella 5.5 data integrity.

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

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)?

    In the UK, probably 50-100.

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.

Survival to discharge
1-year survival

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:

Bleeding
Limb ischaemia
Stroke
Haemolysis
Death

Further comments

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

The device is already in use in the UK advanced HF centres.

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. *

None

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

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

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Stephen Pettit

45. Date: *

08/05/2024

View results

Respondent

79 Anonymous

13:39
Time to complete

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

IP2042 Surgical Insertion of a Catheter based intravascular microaxial blood pump

Your information

2. Name: *

Waqas Akhtar

3. Job title: *

Cardiology & Intensive Care Registrar

4. Organisation: *

GSTT

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

NHS

7. Nominated/ratified by (if applicable):

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

7073628

9. I confirm that:

· I am a registered practising professional in the UK/NHS and in good professional standing

· I have specialist knowledge in the technology or disease area

· I will declare all conflicts of interest in relation to the technology under consideration

· I will abide by NICE's governance policies and comply with NICE's processes and methods

· I will abide by the timelines for this topic, which have been communicated by Zoe Jones.

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

- (●) I agree
- ( ) I do not agree

How NICE will use this information:

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

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

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

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

    Are you familiar with the procedure/technology?

    I have specialised in transplantation and advanced heart failure and worked in units over the last five years that utilises this device regularly

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, have looked after patients regularly with this intervention

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

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

14. Does the title adequately reflect the procedure?

- ( ) Yes
- (•) Should indicate which device it is referring to as there are several

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

I could not see the indication

16. Does this have a multi-indication?

Yes

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

It remains a relatively new technology without any significant randomised evidence. In fact that newest evidence applies to the nonsurgically inserted micro axial flow pump which should be reviewed

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?

Yes, if the evidence supports it may supersede other forms of intermediate mechanical support

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

The device is regularly updated by the manufacturer

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.

As bridging to transplantation variety of different devices such as ECMO, biventricular ventricular assist devices are utilised

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?

Of this specific technology, there are not similar commercially available mechanical support devices

Potential patient benefits and impact on the health system

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

It's off as potential advantages as a lack of need for Sternotomy and quicker recovery post insertion with easier rehabilitation

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

Yes, those waiting for urgent and super urgent Heart transplantation

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, it is already growing in use across Transplant centres for the advantages listed above

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

    Sufficient training and Guidelines on utilisation of the device

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

    Yes, both those inserting and then managing the device afterwards. Particularly in relation to nursing and junior staff who may be managing the patient

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

    Many adverse events possible including during Insertion such as damage to the heart or blood vessel, Perforation of the left ventricle, Haemolysis and infection, arrhythmias

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

Effective bridging to Heart transplantation

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

Still very limited use without any randomised evidence

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

For the ImpellaCP catheter, there is currently an FDA recall

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.

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

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)?

    would estimate this could be between 30 and 40 patients a 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.

    As a bridging strategy to Heart transplantation And as a result, the benefits of this procedure

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

    Adverse outcome measures.

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

    All this things should include insertion complications, Duration of therapy, Failure of device, Infections, Thrombosis and haemolysis, stroke, perforations

Further comments

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

    In view of the New England Journal trial recently published it would be useful to review ImpellaCP as well as the 5.5

Declarations of interests

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

41. Type of interest: *

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

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

Educational grant from Abiomed

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: *

Waqas Akhtar

45. Date: *

09/05/2024