

## View results

Respondent

127

Anonymous

35:00

Time to complete

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

IP2042 Insertion of a catheter-based intravascular microaxial flow pump for cardiogenic shock

## Your information

### 2. Name: \*

Espeed Khoshbin

### 3. Job title: \*

Consultant in Cardiac Surgery, Transplantation and Mechanical Circulatory Support

### 4. Organisation: \*

Royal Brompton and Harefield Hospital as part of Guys and St Thomas NHS Trust

### 5. Email address: \*

[REDACTED]

### 6. Professional organisation or society membership/affiliation: \*

Society of Cardiothoracic Surgeons GB and I

### 7. Nominated/ratified by (if applicable):

Society of Cardiothoracic Surgeons GB and I

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

4292524

9. I confirm that:

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

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

- ☒ I agree
- ☐ I do not agree

### How NICE will use this information:

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

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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

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

- ☒ I agree
- ☐ I disagree

### The procedure/technology

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

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

Are you familiar with the procedure/technology?

Yes I am.

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 I currently use it. It is not as widely used as it should.  
Cardiologists also use it.  
I am experienced in using this technology routinely in patients with cardiogenic shock

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.
- ☐ Other

14. Does the title adequately reflect the procedure?

- ☒ Yes
- ☐ No
- ☐ Other

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

Yes

16. Does this have a multi-indication?

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 is not new

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?

As an addition to the standard of care

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

no

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

☒ Yes

☐ No

### Current management

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

ECMO or ventricular assist devices

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?

Bridge to recovery, Bridge to Bridge, or Bridge to transplantation

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

Patients with isolated LV dysfunction

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?

no

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

screening, TOE and equip operating room.

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

Haemolysis, heart valve injury, vascular injury and ischaemia. Pericardial tamponad.

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

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

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

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.

Shunsuke Saito MD, PhD, Shohei Okubo MD, Taiki Matsuoka MD, Shotaro Hirota MD, Shohei Yokoyama MD, Yuta Kanazawa MD, Yusuke Takei MD, Masahiro Tezuka MD, Go Tsuchiya MD, PhD, Taisuke Konishi MD, PhD, Ikuko Shibasaki MD, PhD, Koji Ogata MD, PhD, Hirotsugu Fukuda MD, PhD, FJCC. Impella – Current issues and future expectations for the percutaneous, microaxial flow left ventricular assist device. *Journal of Cardiology* Volume 83, Issue 4, April 2024, Pages 228-235.

Francesco Burzotta, Carlo Trani, Sagar N. Doshi, Jonathan Townend, Robert Jan van Geuns, Patrick Hunziker, Bernhard Schieffer, Konstantinos Karatolios, Jacob Eifer Møller, Flavio L. Ribichini, Andreas Schäfer, José P.S. Impella ventricular support in clinical practice: Collaborative viewpoint from a European expert user group: *International Journal of Cardiology*; Volume 201, 15 December 2015, Pages 684-691

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

yes

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)?

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.

Recovery from cardiogenic shock, Bridge to transplantation.

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:

Haemolysis, Stroke.

## Further comments

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

There is need in further research into the limitations of this procedure and its scope of use.

## 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
- ☒ No interests to declare

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

nil

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: \*

Espeed Khoshbin

45. Date: \*

16/05/2025



## Professional Expert Questionnaire

**Technology/Procedure name & indication:**

### Your information

|                                                                     |                                                                            |
|---------------------------------------------------------------------|----------------------------------------------------------------------------|
| <b>Name:</b>                                                        | <input type="text" value="Avais Jabbar"/>                                  |
| <b>Job title:</b>                                                   | <input type="text" value="Consultant interventional cardiologist"/>        |
| <b>Organisation:</b>                                                | <input type="text" value="James Cook University Hospital, Middlesbrough"/> |
| <b>Email address:</b>                                               | <input type="text" value=""/>                                              |
| <b>Professional organisation or society membership/affiliation:</b> | <input type="text" value="British Cardiovascular Intervention Society"/>   |
| <b>Nominated/ratified by (if applicable):</b>                       | <input type="text" value="Click here to enter text."/>                     |
| <b>Registration number (e.g. GMC, NMC, HCPC)</b>                    | <input type="text" value="7040882"/>                                       |

### How NICE will use this information:

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

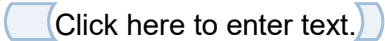
☒ Please tick this box if you would like to receive information about other NICE topics.

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see [our privacy notice](#).**

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



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

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
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| <p><b>1</b> Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"><li>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?</li><li>– Is this procedure/technology performed/used by clinicians in specialities other than your own?</li></ul> | <p>I have had experience with Impella mechanical support whilst I was final year interventional registrar at Harefield Hospital, which is one of the major transplant centres in the country.</p> <p>I am currently working as a consultant interventionist at James Cook University Hospital. As a consultant, I have taken on a leadership role by setting up the Impella service at The James Cook Hospital. I have written the standard operating procedure (SOP), submitted an application to the Clinical Techniques &amp; Procedures Group and presented at their group meeting for device approval. Furthermore, I have provided Imeplla training for the ITU, CCU and cath lab staff. I have provided training in all aspects of Impella management from set up to insertion, as well as all trouble shooting problems encountered during after care management in an ITU and CCU setting.</p> <p>I am currently using it. The use of the device differs according to different centres. Transplant centres such as Harefield Hospital in London, the Freeman Hospital in Newcastle and the Queen Elizabeth Hospital in Birmingham use the device more frequently due to funding. There are now many centres which are using the device in a cardiogenic shock setting related to ST elevation MI (STEMI); as well as high risk percutaneous coronary intervention (PCI).</p> <p>The Imeplla 5.0 is being used by the surgical team in bypasss patients to provide haemodynamic support. The Impella 5.0 is also being in severe LV dysfunction as a bridge to recovery or bridge to transplantation.</p> |
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|   | <ul style="list-style-type: none"> <li>- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.</li> </ul>                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2 | <ul style="list-style-type: none"> <li>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</li> </ul>                                                                                                                                                                   | <p>I have done bibliographic research on this procedure.</p> <p>I have done research on this procedure in laboratory settings (e.g. device-related research).</p> <p>I have done clinical research on this procedure involving patients or healthy volunteers.</p> <p>I have published this research.</p> <p><b>I have had no involvement in research on this procedure.</b></p> <p>Other (please comment)</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 3 | <p>Does the title adequately reflect the procedure?</p> <p>Is the proposed indication appropriate? If not, please explain.</p> <p>Does this have a multi-indication?</p> <p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> | <p>The title does reflect the procedure. At present, the only evidence for its use is in a cardiogenic shock setting as per the renowned Danish–German Cardiogenic (DanGer) Shock Trial, published within the New England Journal of Medicine (Moller, et al., New England Journal of Medicine, 7 Apr 2024) confirming an Impella linked survival benefit. It was found that routine use of Impella CP in patients who have had a STEMI with cardiogenic shock reduced the 180-day mortality by 12.7% compared to the control arm (45.8% vs. 58.5%, p=0.04). The number needed to treat to avoid 1 death was 8.</p> <p>The device is also used in a high risk non emergency PCI setting which includes patients with complex coronary disease defined by: a British Cardiovascular Intervention Society (BCIS) Jeopardy Score <math>\geq 8</math>, severe left ventricular systolic dysfunction defined as a LVEF <math>\leq 35\%</math>, the need for complex calcium modification in the left main stem or where the syntax score is <math>\geq 32</math>. Although there is no evidence for this, trials are ongoing and recruiting patients to Impella use in a high risk PCI staged setting such as the CHIP-BCIS3 and The PROTECT IV Trials.</p> <p>Prior to the DanGER shock Trial, there was no evidence for any mechanical support device and its use in cardiogenic shock with regard to a survival benefit. We traditionally used the intra aortic balloon pump (IABP) although trial data showed no benefit in its use in reducing mortality or major adverse cardiovascular events (MACE).</p> |

|   |                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | Which of the following best describes the procedure (please choose one):                                                                                                                                                                                                    | <p>Established practice and no longer new.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p> <p>Definitely novel and of uncertain safety and efficacy.</p> <p><b>The first in a new class of procedure.</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 4 | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?                                                                                                                            | <p>Prior to the DanGer Shock Trial of Impella use, there was no current standard care for cardiogenic shock in a myocardial infarction setting. Devices such as the intra aortic balloon pump and extracorporeal membrane oxygenation (ECMO) in trials did not demonstrate a survival benefit in cardiogenic shock.</p> <p>Recent systematic reviews of the evidence for LV unloading in high-risk PCI have been conducted by NICE and Health Quality Ontario. Both concluded that there is currently inadequate data to make any strong recommendation as to the use of LV unloading in high-risk PCI.</p> <p>There are no randomised data on the safety and efficacy of LV unloading assisted PCI compared to the current standard of care (PCI without mechanical support).</p> |
| 5 | <p>Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?</p> <p>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?</p> | N/A                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |

## Current management

|   |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                   |
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| 6 | Please describe the current standard of care that is used in the NHS.                                                                                                                                                                                 | The standard care in many centres is the use of Impella if the device is accessible. This is in both a cardiogenic shock setting as well as a high risk PCI setting. Other centres are still using the intra aortic balloon pump despite no evidence for its use. |
| 7 | <p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p> | <p>N/A</p> <p>No other device has been proven to reduce MACE and improve outcomes in a clinical shock trial.</p>                                                                                                                                                  |

### Potential patient benefits and impact on the health system

|   |                                                                                                       |                                                                                                                                                                                                           |
|---|-------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8 | What do you consider to be the potential benefits to patients from using this procedure/technology?   | There is a benefit in MACE which is driven by mortality. Preventing major periprocedural complications, which in turn would be expected to reduce mortality, critical care admissions and length of stay. |
| 9 | Are there any groups of patients who would particularly benefit from using this procedure/technology? | The device has to be used in those patients in whom there will be a mortality benefit as per the DanGer Shock inclusion criteria.                                                                         |

|  |  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
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|  |  | <p>Inclusion:</p> <ul style="list-style-type: none"> <li>• Age <math>\geq 18</math> years</li> <li>• STEMI</li> <li>• Cardiogenic shock, hypotension (systolic blood pressure <math>&lt; 100</math> mm Hg or an ongoing need for vasopressor support), end-organ hypoperfusion with an arterial lactate level of <math>\geq 2.5</math> mmol/L, and a left ventricular ejection fraction of <math>&lt; 45\%</math>)</li> <li>• Shock duration less than <math>\leq 24</math> hours</li> <li>• STEMI where shock develops during or up to 12 hours after revascularisation</li> </ul> <p>Exclusion:</p> <ul style="list-style-type: none"> <li>• Mechanical complication to MI; papillary muscle rupture, rupture of the ventricular septum or rupture of ventricular free wall</li> <li>• Out-of-hospital cardiac arrest with persistent Glasgow coma scale <math>&lt; 8</math> after return of spontaneous circulation. Cardiac arrest occurring in ambulance or after arrival to hospital is not an exclusion criterion</li> <li>• Left ventricular thrombus</li> <li>• Severe RV failure on echocardiogram <ul style="list-style-type: none"> <li>- To be assessed on individual basis</li> <li>- RV dilatation on TTE, tapse <math>&lt; 1</math> cm</li> <li>- Septal shift should raise concerns</li> </ul> </li> <li>• Severe peripheral arterial obstructive disease that would preclude Impella device placement</li> <li>• Mechanical aortic valve prosthesis</li> <li>• Severe aorta valve regurgitation/stenosis</li> </ul> |
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|    |                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
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| 10 | <p>Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?</p> <p>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?</p> | <p>With the increase use in Impella, there will likely be the development of regional shock centres with experts in device insertion. Its application has already been applied in non shock centres. Clinical outcomes are likely to change in view of this being the first device which has a proven mortality benefit.</p>                                                                                                                                                                                                                                                                           |
| 11 | <p>What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?</p>                                                                                                                                   | <p>Training provided by the Abiomed regional representative or a proctor to all the cath lab, ITU and CCU teams with regard to device insertion and the after care of patients in an ITU and CCU setting.</p> <p>Experts in managing large bore peripheral access is an essential prerequisite as this is a 14fr device. It is integral there is at least one operator with experience in large bore access. Many centres already have a well established TAVI service with operators undertaking large bore access.</p> <p>All centres will need to develop a standard operating procedure (SOP).</p> |
| 12 | <p>Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?</p>                                                                                                                                      | <p>Training by the Abiomed regional representative and proctor is integral prior to commencing an Impella programme.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |

### Safety and efficacy of the procedure/technology

|    |                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 13 | <p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> | <ol style="list-style-type: none"> <li>1. Bleeding complications due to insertion via the femoral artery. Bleeding is reduced by deploying two perclose sutures prior to the device being inserted.</li> <li>2. Thrombosis around the device – this is an infrequent occurrence due to patients being on systemic heparin whilst the device is in situ. Thrombosis poses the risk of profound haemolysis and thrombus embolism.</li> <li>3. Limb ischaemia – this is reduced by removing the 14fr peel away sheath at the end of the procedure if the device is to remain in.</li> </ol> |
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|  |                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
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|  | Theoretical adverse events | <p>4. Acute kidney injury defined as prolongation hospital admission or readmission <math>\geq 24</math> hours with rise in creatinine to 200% of baseline value or need for new renal replacement therapy within 30 days of procedure.</p> <p>5. Vascular major complication:</p> <ul style="list-style-type: none"> <li>• Aortic dissection or aortic rupture</li> <li>• Vascular (arterial or venous) injury# or compartment syndrome resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischaemia, or irreversible neurologic impairment</li> <li>• Distal embolization (non-cerebral) from a vascular source resulting in death, amputation, limb or visceral ischaemia, or irreversible end-organ damage</li> <li>• Unplanned endovascular or surgical intervention resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischaemia, or irreversible neurologic impairment</li> <li>• Closure device failure resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischaemia, or irreversible neurologic impairment</li> </ul> <p>6. Vascular minor complication:</p> <ul style="list-style-type: none"> <li>• Vascular (arterial or venous) injury not resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischaemia, or irreversible neurologic impairment</li> <li>• Distal embolization treated with embolectomy and/or thrombectomy, not resulting in death, amputation, limb or visceral ischaemia, or irreversible end-organ damage</li> <li>• Any unplanned endovascular or surgical intervention, ultra-sound guided compression, or thrombin injection, not resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischaemia, or irreversible neurologic impairment</li> <li>• Closure device failure not resulting in death, VARC type <math>\geq 2</math> bleeding, limb or visceral ischaemia, or irreversible neurologic impairment</li> </ul> <p>In the DanGer Shock Trial, A composite safety end-point event occurred in 43 patients (24.0%) in the microaxial-flow-pump group and in 11 (6.2%) in the standard-care group (relative risk, 4.74; 95% CI, 2.36 to 9.55) (Table 3 and Fig. S7). In the microaxial-flow-pump group, the number needed to harm was 6. The relative risk (microaxial-flow-pump group vs. standard-care group) of moderate or severe bleeding was 2.06 (95% CI, 1.15 to 3.66); of limb ischemia, 5.15</p> |
|--|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|    |                                                                                                            |                                                                                                                                                                                                       |
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|    |                                                                                                            | (95% CI, 1.11 to 23.84); of renal-replacement therapy, 1.98 (95% CI, 1.27 to 3.09); and of sepsis with a positive blood culture, 2.79 (95% CI, 1.20 to 6.48).                                         |
| 14 | Please list the key efficacy outcomes for this procedure/technology?                                       | Impella efficacy outcomes in cardiogenic shock and high-risk PCI include improved survival rates, myocardial recovery, and successful bridging to other therapies.                                    |
| 15 | Please list any uncertainties or concerns about the efficacy and safety of this procedure/?                | Carries risks of complications like bleeding and vascular issues.                                                                                                                                     |
| 16 | Is there controversy, or important uncertainty, about any aspect of the procedure/technology?              | N/A                                                                                                                                                                                                   |
| 17 | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | <p>Most or all district general hospitals.</p> <p><b>A minority of hospitals, but at least 10 in the UK.</b></p> <p>Fewer than 10 specialist centres in the UK.</p> <p>Cannot predict at present.</p> |

### Abstracts and ongoing studies

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                                       |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|
| 18 | <p>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).</p> <p>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</p> | <p>Microaxial Flow Pump or Standard Care in Infarct-Related Cardiogenic Shock</p> <p>N Engl J Med. 2024 Apr 18;390(15):1382-1393.</p> |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------|

|           |                                                                                                                  |                                                                                                                                |
|-----------|------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
|           | us if you list any that you think are particularly important.                                                    |                                                                                                                                |
| <b>19</b> | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | trials which are recruiting patients to Impella use in a high risk PCI staged setting are CHIP-BCIS3 and The PROTECT IV Trial. |
| <b>20</b> | Please list any other data (published and/or unpublished) that you would like to share.                          |                                                                                                                                |

### Other considerations

|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>21</b> | 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)?                                                                                                                                                                                                                                                                                                                                                                                                                    | <p>For example, The James Cook University Hospital is a busy tertiary centre. We are one of the biggest units in the country performing 1600 PCIs per annum. We insert around 6 devices per annum whilst applying the strict DanGer Shock Criteria and selecting patients who will benefit from Impella in cardiogenic shock.</p> <p>The use of the device will likely increase if the CHIP-BCIS3 and The PROTECT IV Trials are positive, to support its use in a high risk PCI setting outside of shock.</p>                                                                                                                                                                                                                                                                                                    |
| <b>22</b> | <p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> <li>– 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.</li> <li>– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:</li> </ul> | <p>Beneficial outcome measures:</p> <p>Mortality and escalation to other treatment despite Impella support (such as VA ECMO and LVAD). LV unloading could provide clinical benefit via two distinct mechanisms – firstly, by preventing major periprocedural complications, which in turn would be expected to reduce mortality, critical care admissions and length of stay; secondly, by allowing operators to undertake more complex and complete revascularisation, the latter having been shown to be associated with improved mortality, reduced rehospitalisation and subsequently improved health-related quality of life</p> <p>Adverse outcome measures:</p> <p>Moderate or severe bleeding, limb ischemia, stroke, receipt of renal-replacement therapy, and sepsis with positive blood cultures.</p> |

### Further comments

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

## Declarations of interests

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

| Type of interest * | Description of interest                   | Relevant dates |                 |
|--------------------|-------------------------------------------|----------------|-----------------|
|                    |                                           | Interest arose | Interest ceased |
| Choose an item.    | No disclosures or declaration of interest |                |                 |
| Choose an item.    |                                           |                |                 |
| Choose an item.    |                                           |                |                 |

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

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

|             |                                           |
|-------------|-------------------------------------------|
| Print name: | <input type="text" value="Avais Jabbar"/> |
| Dated:      | <input type="text" value="24/06/25"/>     |

## Professional Expert Questionnaire

**Technology/Procedure name & indication:**

### Your information

|                                                                     |                                                                           |
|---------------------------------------------------------------------|---------------------------------------------------------------------------|
| <b>Name:</b>                                                        | <input type="text" value="Dawn Adamson"/>                                 |
| <b>Job title:</b>                                                   | <input type="text" value="National Specialty Advisor for Heart Disease"/> |
| <b>Organisation:</b>                                                | <input type="text" value="NHSE"/>                                         |
| <b>Email address:</b>                                               | <input type="text" value="[REDACTED]"/>                                   |
| <b>Professional organisation or society membership/affiliation:</b> | <input type="text" value="GMC, BCS, BCIS, UKMCS"/>                        |
| <b>Nominated/ratified by (if applicable):</b>                       | <input type="text" value="Click here to enter text."/>                    |
| <b>Registration number (e.g. GMC, NMC, HCPC)</b>                    | <input type="text" value="4025797"/>                                      |

### How NICE will use this information:

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

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

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see [our privacy notice](#).**

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

 Click here to enter text. 

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

|                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>1</b> Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"><li>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?</li><li>– Is this procedure/technology performed/used by clinicians in specialities other than your own?</li></ul> | <p>I am consultant interventional cardiologist who works clinically as well as NSA for Heart disease for NHSE. I am familiar with the device and in the past have used it but it isn't currently available in the trust.</p> <p>I am on the CRG and have been looking into its use and whether we are at the stage to suggest a policy proposition for specialised commissioning, and am leading on cardiogenici shock network developments from an NHSE point of view.</p> <p>We are aware it is being used both within and out of scope ie the predominant trial DANGER shock had very specific criteria for inclusion within the trial.</p> |
|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|   |                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | <ul style="list-style-type: none"> <li>- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.</li> </ul>                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
| 2 | <ul style="list-style-type: none"> <li>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</li> </ul>                                                                                                                                                                                                                                                   | <p>I am aware of the research, I have sat on BCIS ACI expert panels when the Danger shock trial is being presented, but am not actively involved in research on this subject myself</p> <p>Other (please comment)</p>                                                                                                                                                                                                                                                                                                                             |
| 3 | <p>Does the title adequately reflect the procedure?</p> <p>Is the proposed indication appropriate? If not, please explain.</p> <p>Does this have a multi-indication?</p> <p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p> | <p>Yes</p> <p>It is providing the criteria which have been proven to show efficacy with this product are followed</p> <p>There is a further trial BCIS CHIP 3 assessing the use of Impella in high risk coronary intervention which is due to report next year</p> <p>Impella has been around for around 20 years, but only recently has there been a positive randomised trial which has ignited interest within its use.</p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p> |
| 4 | Does this procedure/technology have the potential to replace current standard care or                                                                                                                                                                                                                                                                                                                              | This would be used in addition to standard of care in specific patient cohorts                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

|   |                                                                                                                                                                                                                                                                             |                                                                                                                                                                 |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | would it be used as an addition to existing standard care?                                                                                                                                                                                                                  |                                                                                                                                                                 |
| 5 | <p>Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?</p> <p>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?</p> | I am not aware of significant changes in procedure technique, but increased awareness that with the correct patient cohort selection, outcomes can be positive. |

### Current management

|   |                                                                                                                                                                                                                                                       |                                                                                                                                                      |
|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6 | Please describe the current standard of care that is used in the NHS.                                                                                                                                                                                 | Impella's are used across the country in PPCI centres predominantly but are currently not commissioned within NHSE                                   |
| 7 | <p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p> | <p>There are technologies which have lower or higher ability to off load the heart.</p> <p>There is the IABP which is lower, then VAD is higher.</p> |

### Potential patient benefits and impact on the health system

|    |                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8  | What do you consider to be the potential benefits to patients from using this procedure/technology?                                                                                                                                               | In the correct cohort, there is some patient survival benefit in cardiogenic shock                                                                                                                                                                                                                                                                                                                                                             |
| 9  | Are there any groups of patients who would particularly benefit from using this procedure/technology?                                                                                                                                             | See Danger shock inclusion criteria                                                                                                                                                                                                                                                                                                                                                                                                            |
| 10 | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br><br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | There could be improved survival, however that is if the device is used in the specific selected cohorts described within the danger shock trial.<br><br>This however comes at a cost as the devices are expensive and staff training and competence in using the device frequently enough needs to be factored in. It is also recognised that there are complications, mainly around vascular access which need to be taken into account also |
| 11 | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?                                                                                                                                   | Cardiac cath lab to insert the device and an appropriately trained CCU/ITU to manage the patient.                                                                                                                                                                                                                                                                                                                                              |
| 12 | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?                                                                                                                                      | Need to be trained in placing device then monitoring and managing the device, as well as removing it                                                                                                                                                                                                                                                                                                                                           |

### Safety and efficacy of the procedure/technology

|    |                                                                                                                                                                                    |                                        |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|
| 13 | What are the potential harms of the procedure/technology?<br><br>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: | Predominantly vascular access problems |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------|

|           |                                                                                                                                                                                  |                                                                                                                                                                                                |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           | <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p> |                                                                                                                                                                                                |
| <b>14</b> | Please list the key efficacy outcomes for this procedure/technology?                                                                                                             |                                                                                                                                                                                                |
| <b>15</b> | Please list any uncertainties or concerns about the efficacy and safety of this procedure/?                                                                                      | Ensuring the staff are competent to manage the device and it's complications – do we need a minimum number implanted a year to have that competence                                            |
| <b>16</b> | Is there controversy, or important uncertainty, about any aspect of the procedure/technology?                                                                                    | Only in the selection criteria for those who benefit                                                                                                                                           |
| <b>17</b> | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):                                                                       | <p>Most or all district general hospitals.</p> <p>A minority of hospitals, but at least 10 in the UK.</p> <p>Fewer than 10 specialist centres in the UK.</p> <p>Cannot predict at present.</p> |

### Abstracts and ongoing studies

|           |                                                                                                                                                                                                                                                                                                                  |                                          |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|
| <b>18</b> | <p>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).</p> <p>Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent</p> | Session at ACI ( BCIS annual conference) |
|-----------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------|

|           |                                                                                                                                                                                                                                          |             |
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|           | 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. |             |
| <b>19</b> | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.                                                                                                                         | BCIS-CHIP 3 |
| <b>20</b> | Please list any other data (published and/or unpublished) that you would like to share.                                                                                                                                                  |             |

### Other considerations

|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                       |
|-----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>21</b> | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?                                                                                                                                                                                                                                                                                                                                                          | 10% of all STEMI in shock                                                                                                                                                             |
| <b>22</b> | <p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> <li>– 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.</li> <li>– Adverse outcome measures. These should include early and late complications. Please state the post</li> </ul> | <p>Beneficial outcome measures:</p> <p>Survival</p> <p>LV systolic function</p> <p>Adverse outcome measures:</p> <p>Death</p> <p>Need for vascular intervention</p> <p>Blood loss</p> |

|  |                                                           |  |
|--|-----------------------------------------------------------|--|
|  | procedure timescales over which these should be measured: |  |
|--|-----------------------------------------------------------|--|

### Further comments

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

## Declarations of interests

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

| Type of interest *                | Description of interest                                                                                                                                                                                                          | Relevant dates |                 |
|-----------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------|-----------------|
|                                   |                                                                                                                                                                                                                                  | Interest arose | Interest ceased |
| <i>Non-financial professional</i> | I am on the CRG which would review any policy propositions submitted for use of this device and currently I have suggested we hold commissioning whilst we evaluate it's use further and start the development of shock networks | Jan 25         |                 |
| Choose an item.                   |                                                                                                                                                                                                                                  |                |                 |
| Choose an item.                   |                                                                                                                                                                                                                                  |                |                 |

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

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

|             |                                              |
|-------------|----------------------------------------------|
| Print name: | <input type="text" value="Dr Dawn Adamson"/> |
| Dated:      | <input type="text" value="25/06/2025"/>      |

## Professional Expert Questionnaire

**Technology/Procedure name & indication:**

### Your information

|                                                                     |                                                                                                                                                                                                          |
|---------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name:</b>                                                        | <input type="text" value="Mr Harikrishna Doshi"/>                                                                                                                                                        |
| <b>Job title:</b>                                                   | <input type="text" value="Consultant Cardiac and Transplant Surgeon"/>                                                                                                                                   |
| <b>Organisation:</b>                                                | <input type="text" value="Golden Jubilee National University Hospital"/>                                                                                                                                 |
| <b>Email address:</b>                                               | <input type="text" value=""/>                                                                                                                                                                            |
| <b>Professional organisation or society membership/affiliation:</b> | <input type="text" value="Deputy Chair: Adult Cardiac Surgery subcommittee of Society of Cardiothoracic Surgery of Great Britain and Ireland (SCTS), Senior Clinical Lecturer (University of Glasgow)"/> |
| <b>Nominated/ratified by (if applicable):</b>                       | <input type="text" value="Click here to enter text."/>                                                                                                                                                   |
| <b>Registration number (GMC)</b>                                    | <input type="text" value="5179693"/>                                                                                                                                                                     |

### How NICE will use this information:

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

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

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see [our privacy notice](#).**



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

 Click here to enter text. 

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

|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <p>Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"><li>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?</li><li>– Is this procedure/technology performed/used by clinicians in specialities other than your own?</li></ul> | <p><b>I am practicing as Consultant Cardiac and Transplant surgeon at Golden Jubilee National University Hospital from November 2016. I am well versed with the use of Mechanical Cardiac support devices including surgical use of Catheter based intravascular axial flow pumps. I have used them successfully in number of patients including their explant and leading on to their use as Bridge to Heart Transplant.</b></p> <p><b>I have used catheter based axial flow pumps as treatment modality to treat patients with acute heart failure presenting with refractory cardiogenic shock. My understanding is that these pumps are routinely used by commissioned units across United Kingdom. I believe that there is growing need for these pumps with increasing number of patients referred with heart failure, as is demonstrated by recent NICOR data.</b></p> |
|----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|   |                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|---|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | <ul style="list-style-type: none"> <li>- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.</li> </ul>                                                                                                                    | <p><b>These pumps come in different sizes and capacity of flows. Smaller size and flow pumps tend to be used by Cardiologists and bigger size pumps requires insertion through subclavian arteries and are inserted by cardiac surgeon in operation theatre.</b></p>                                                                                                                                                                                              |
| 2 | <ul style="list-style-type: none"> <li>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</li> </ul>                                                                                                                                                                   | <p><u><b>I have done bibliographic research on this procedure.</b></u></p> <p><del>I have done research on this procedure in laboratory settings (e.g. device-related research).</del></p> <p><del>I have done clinical research on this procedure involving patients or healthy volunteers.</del></p> <p><del>I have published this research.</del></p> <p><del>I have had no involvement in research on this procedure.</del></p> <p>Other (please comment)</p> |
| 3 | <p>Does the title adequately reflect the procedure?</p> <p>Is the proposed indication appropriate? If not, please explain.</p> <p>Does this have a multi-indication?</p> <p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> | <p><b>Yes</b></p> <p><b>Yes</b></p> <p><b>Established practice and no longer new.</b></p> <p>A minor variation on an existing procedure, which is unlikely to alter the procedure's safety and efficacy.</p> <p>Definitely novel and of uncertain safety and efficacy.</p> <p>The first in a new class of procedure.</p>                                                                                                                                          |

|   |                                                                                                                                                                                                                                                                             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
|---|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | Which of the following best describes the procedure (please choose one):                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |
| 4 | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?                                                                                                                            | <p><b>No</b></p> <p><b>Flow axial pumps are better at reducing LV workload however, they do not provide Oxygenator (Gas exchange capability) and does not support right ventricle (RV: which will require insertion of another pump to support, if it needs). ECMO provides support for both ventricles however, it does not unload the left ventricle (LV: some cases of ECMO will require additional LV vent).</b></p>                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 5 | <p>Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?</p> <p>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?</p> | <p><b>Established devices and their use by multiple centres in its current forms.</b></p> <p><b>Being a new type of mechanical cardiac support device, there is growing experience and clinical evidence of its use over recent years. There is also growing evidence of the potential complications and requirement for prompt intervention required to rectify them. Currently, British societies including Faculty of Intensive care medicine, Resuscitation council of UK, British society of heart failure, British association of critical care nurses, Society of cardiothoracic surgery of Great Britain and Ireland, British cardiovascular society, and association of cardiothoracic anaesthesia and critical care are working on “guidelines on the management of emergencies in patients with left sided Impella therapy”.</b></p> |

### Current management

|   |                                                                       |                                                                                                                                                            |
|---|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 6 | Please describe the current standard of care that is used in the NHS. | <p><b>Patients requiring Mechanical Cardiac support with Cardiogenic shock receives peripheral or central ECMO using mechanical centrifugal pumps.</b></p> |
|---|-----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|

|                                                                                                                                                                                                                                                                |                  |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|
| <p><b>7</b> 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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p> | <p><b>No</b></p> |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|

## Potential patient benefits and impact on the health system

|    |                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8  | What do you consider to be the potential benefits to patients from using this procedure/technology?                                                                                                                                               | <b>Catheter based axial flow pumps can be inserted percutaneously. Larger devices which carried more volume of blood, needs insertion through the subclavian arteries but due to its smaller nature compared to ECMO pumps, it allows ambulation to patients. Flow axial pumps can completely unload the left ventricle making them unique in that respect and thus even in patients with ECMO, they can be used to unload the left ventricle. This strategy is increasingly used in many international and national centres is popularly called as ECPELA. There is also growing evidence to suggest that flow axial pumps have lower complications compared to ECMO such as infection, bleeding, distal limb ischaemia and stroke.</b> |
| 9  | Are there any groups of patients who would particularly benefit from using this procedure/technology?                                                                                                                                             | <b>Patients with refractory Cardiogenic shock requiring mechanical cardiac support in the cathlab (for example, during high risk revascularisation) or patients referred for consideration for mechanical cardiac support to transplant surgeons as bridge to candidacy, recovery of transplantation.</b>                                                                                                                                                                                                                                                                                                                                                                                                                                |
| 10 | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br><br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | <b>Yes. It will allow better outcomes in patients undergoing high risk revascularisation in cathlab. Early identification and treatment of Cardiogenic shock has shown significant improvement in outcomes. Some of these patients will eventually be referred for consideration of cardiac transplant and early selection of these patients may allow progress to Cardiac transplantation form these pumps without need to escalate them to BiVAD support thus leading to cost savings and reduction in morbidity and mortality.</b>                                                                                                                                                                                                    |
| 11 | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?                                                                                                                                   | <b>Existing facilities are sufficient to use these devices.</b>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| 12 | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?                                                                                                                                      | <b>Extra training is required for nursing and ICU staff. As mentioned before, Currently, British societies including Faculty of Intensive care medicine, Resuscitation council of UK, British society of heart failure, British association of critical care nurses, Society of cardiothoracic surgery of Great Britain and Ireland, British cardiovascular society, and association of cardiothoracic anaesthesia and critical care are working on “guidelines on the management of emergencies in patients with left sided Impella therapy” which will lead to prompt and uniform delivery of care in cases of complications for patients with these devices.</b>                                                                      |

## Safety and efficacy of the procedure/technology

|    |                                                                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
|----|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 13 | <p>What are the potential harms of the procedure/technology?</p> <p>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:</p> <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p> | <p>Frequency depends on size of device: Bleeding, Infection, distal limb ischaemia, stroke, death.</p> <ol style="list-style-type: none"> <li>1. Saito Y, Tateishi K, Toda K, Matsumiya G, Kobayashi Y; J-PVAD registry study investigators. Complications and Outcomes of Impella Treatment in Cardiogenic Shock Patients With and Without Acute Myocardial Infarction. J Am Heart Assoc. 2023 Sep 5;12(17):e030819. doi: 10.1161/JAHA.123.030819. Epub 2023 Aug 30. PMID: 37646217; PMCID: PMC10547360.</li> <li>2. Ardito V, Sarucanian L, Rognoni C, Pieri M, Scandroglia AM, Tarricone R. Impella Versus VA-ECMO for Patients with Cardiogenic Shock: Comprehensive Systematic Literature Review and Meta-Analyses. J Cardiovasc Dev Dis. 2023 Apr 5;10(4):158. doi: 10.3390/jcdd10040158. PMID: 37103037; PMCID: PMC10142129.</li> <li>3. Vora N, Chaudhary R, Upadhyay HV, Konat A, Zalavadia P, Padaniya A, Patel P, Patel N, Prajjwal P, Sharma K. Mechanical Assist Device-Assisted Percutaneous Coronary Intervention: The Use of Impella Versus Extracorporeal Membrane Oxygenation as an Emerging Frontier in Revascularization in Cardiogenic Shock. Cureus. 2023 Jan 4;15(1):e33372. doi: 10.7759/cureus.33372. PMID: 36751242; PMCID: PMC9898582.</li> </ol> |
| 14 | <p>Please list the key efficacy outcomes for this procedure/technology?</p>                                                                                                                                                                                                                                                                                                | <p>Improvement in LV unloading and recovery</p> <p>Improved organ perfusion</p> <p>Bridge to decision, recovery or transplantation</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       |
| 15 | <p>Please list any uncertainties or concerns about the efficacy and safety of this procedure/?</p>                                                                                                                                                                                                                                                                         | <p>Uncertainty regarding best device to use in patients with refractory cardiogenic shock: ECMO versus axial flow pumps but there is growing evidence to suggest that there is a definite place for axial flow pumps in these very difficult group of patients.</p> <p>Potential for complications is high as mentioned in section 13 but we need to keep in mind that patients with refractory cardiogenic shock do not have other option and will have almost certainty of death if not intervened with Mechanical cardiac support.</p>                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

|    |                                                                                                            |                                                                                                                                                                                                              |
|----|------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 16 | Is there controversy, or important uncertainty, about any aspect of the procedure/technology?              | No                                                                                                                                                                                                           |
| 17 | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one): | <p>Most or all district general hospitals.</p> <p>A minority of hospitals, but at least 10 in the UK.</p> <p><b><u>Fewer than 10 specialist centres in the UK.</u></b></p> <p>Cannot predict at present.</p> |

### Abstracts and ongoing studies

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 18 | <p>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).</p> <p>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.</p> | <ol style="list-style-type: none"> <li>1. Møller JE, Engstrøm T, Jensen LO, Eiskjær H, Mangner N, Polzin A, Schulze PC, Skurk C, Nordbeck P, Clemmensen P, Panoulas V, Zimmer S, Schäfer A, Werner N, Frydland M, Holmvang L, Kjærgaard J, Sørensen R, Lønborg J, Lindholm MG, Udesen NLJ, Junker A, Schmidt H, Terkelsen CJ, Christensen S, Christiansen EH, Linke A, Woitek FJ, Westenfeld R, Möbius-Winkler S, Wachtell K, Ravn HB, Lassen JF, Boesgaard S, Gerke O, Hassager C; DanGer Shock Investigators. Microaxial Flow Pump or Standard Care in Infarct-Related Cardiogenic Shock. <i>N Engl J Med</i>. 2024 Apr 18;390(15):1382-1393. doi: 10.1056/NEJMoa2312572. Epub 2024 Apr 7. PMID: 38587239.</li> <li>2. Tariq MD, Jain H, Khan AM, Shahnoor S, Goyal P, Zulfiqar E, Ahsan A, Jaiswal V, Daoud M, Sohail AH. Efficacy and safety of percutaneous mechanical circulatory support in patients with cardiogenic shock following acute myocardial infarction: A meta-analysis of randomized controlled trials. <i>Medicine (Baltimore)</i>. 2024 Nov 15;103(46):e40595. doi: 10.1097/MD.00000000000040595. PMID: 39560531; PMCID: PMC11576003.</li> <li>3. Saito Y, Tateishi K, Toda K, Matsumiya G, Kobayashi Y; J-PVAD registry study investigators. Complications and Outcomes of Impella Treatment in Cardiogenic Shock Patients With and Without Acute Myocardial Infarction. <i>J Am Heart Assoc</i>. 2023 Sep 5;12(17):e030819. doi: 10.1161/JAHA.123.030819. Epub 2023 Aug 30. PMID: 37646217; PMCID: PMC10547360.</li> <li>4. Ardito V, Sarucanian L, Rognoni C, Pieri M, Scandroglio AM, Tarricone R. Impella Versus VA-ECMO for Patients with Cardiogenic Shock: Comprehensive Systematic</li> </ol> |
|----|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|    |                                                                                                                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |
|----|------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|    |                                                                                                                  | <p>Literature Review and Meta-Analyses. J Cardiovasc Dev Dis. 2023 Apr 5;10(4):158. doi: 10.3390/jcdd10040158. PMID: 37103037; PMCID: PMC10142129.</p> <p>5. Vora N, Chaudhary R, Upadhyay HV, Konat A, Zalavadia P, Padaniya A, Patel P, Patel N, Prajjwal P, Sharma K. Mechanical Assist Device-Assisted Percutaneous Coronary Intervention: The Use of Impella Versus Extracorporeal Membrane Oxygenation as an Emerging Frontier in Revascularization in Cardiogenic Shock. Cureus. 2023 Jan 4;15(1):e33372. doi: 10.7759/cureus.33372. PMID: 36751242; PMCID: PMC9898582.</p> |
| 19 | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | <ol style="list-style-type: none"> <li>1. PROTECT IV Randomized Controlled Trial: Ongoing trial to compare complete revascularization PCI with Impella CP to complete revascularization PCI without any planned hemodynamic support.</li> <li>2. ST-Elevation Myocardial Infarction Door-to-Unloading (STEMI DTU) Pivotal Randomized Controlled Trial</li> <li>3. IMPella-Protected cArDiaC Surgery Trial (IMPACT)</li> </ol>                                                                                                                                                      |
| 20 | Please list any other data (published and/or unpublished) that you would like to share.                          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    |

## Other considerations

|    |                                                                                                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                                                                                                     |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 21 | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?                                                                                                                                         | <p>I work at Golden Jubilee National University Hospital, Glasgow which is one of the 6 transplant centres in UK. We have performed 54 mechanical cardiac support (short term) last year. Lot os these patients could have also had flow axial pumps. We have a catchment population of 5.5 million which is much smaller than some of the other centres in UK.</p> |
| 22 | <p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> <li>– Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most</li> </ul> | <p>Beneficial outcome measures:</p> <p><b>Short term:</b></p> <ul style="list-style-type: none"> <li>• Improved organ perfusion leading to reduced stay in ICU</li> <li>• Reduced morbidity shown by reduced rate of use of renal support, infection bleeding and limb ischaemia</li> <li>• Reduced mortality</li> </ul>                                            |

|  |                                                                                                                                                                                                                                                                                                                            |                                                                                                                                                                                                                                                                                                                                                                                   |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|  | <p>appropriate method of measurement for each and the timescales over which these should be measured.</p> <ul style="list-style-type: none"> <li>– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:</li> </ul> | <p><b>Long term:</b></p> <ul style="list-style-type: none"> <li>• <b>Improved survival to discharge</b></li> <li>• <b>Improved survival to transplant</b></li> </ul> <p><b>Adverse outcome measures:</b></p> <ul style="list-style-type: none"> <li>• <b>Complication rates such as bleeding, infection, distal limb ischaemia, stroke</b></li> <li>• <b>Mortality</b></li> </ul> |
|--|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

### Further comments

|           |                                                                                                                                         |  |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------|--|
| <b>23</b> | <p>If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.</p> |  |
|-----------|-----------------------------------------------------------------------------------------------------------------------------------------|--|

## Declarations of interests

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

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

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

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

|             |                                                |
|-------------|------------------------------------------------|
| Print name: | <input type="text" value="Harikrishna Doshi"/> |
| Dated:      | <input type="text" value="5th June 2025"/>     |

## Professional Expert Questionnaire

**Technology/Procedure name & indication:**

### Your information

|                                                                     |                                                                                          |
|---------------------------------------------------------------------|------------------------------------------------------------------------------------------|
| <b>Name:</b>                                                        | <input type="text" value="Mostafa ElAdawy"/>                                             |
| <b>Job title:</b>                                                   | <input type="text" value="Consultant in cardiothoracic anaesthesia and intensive care"/> |
| <b>Organisation:</b>                                                | <input type="text" value="Newcastle upon Tyne hospitals"/>                               |
| <b>Email address:</b>                                               | <input type="text" value=""/>                                                            |
| <b>Professional organisation or society membership/affiliation:</b> | <input type="text" value="GMC"/>                                                         |
| <b>Nominated/ratified by (if applicable):</b>                       | <input type="text" value="Click here to enter text."/>                                   |
| <b>Registration number (e.g. GMC, NMC, HCPC)</b>                    | <input type="text" value="7189047"/>                                                     |

### How NICE will use this information:

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

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

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see [our privacy notice](#).**

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

 Click here to enter text.

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

|          |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                                                                                                                                                                                                                                                                                                                                                                                      |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b> | <p>Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"><li>- Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?</li><li>- Is this procedure/technology performed/used by clinicians in specialities other than your own?</li><li>- If your specialty is involved in patient selection or referral to another specialty for this</li></ul> | <p>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 on a regular basis, I am the clinical lead for Impella in ICU</p> <p>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 intensivists</p> |
|----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|   |                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                                                                                                                     |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | procedure/technology, please indicate your experience with it.                                                                                                                                                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                     |
| 2 | <p>– Please indicate your research experience relating to this procedure (please choose one or more if relevant):</p>                                                                                                                                                                                                                                                                                              | I have had no involvement in research on this procedure.                                                                                                                                                                                                                                                                                                                                                            |
| 3 | <p>Does the title adequately reflect the procedure?</p> <p>Is the proposed indication appropriate? If not, please explain.</p> <p>Does this have a multi-indication?</p> <p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p> | <p>The title does not reflect the procedure in details, it does not specify the type of device (having two different Impella devices in the market now), or the acuity and classification of cardiogenic shock</p> <p>Yes it has multiple indication</p> <p>It is innovative and novel concept</p> <p>Established practice in many centres in the Uk but definitely novel and of uncertain safety and efficacy.</p> |
| 4 | Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?                                                                                                                                                                                                                                                                   | It can be addition or replacement to existing standard care                                                                                                                                                                                                                                                                                                                                                         |
| 5 | Have there been any substantial modifications to the procedure technique or,                                                                                                                                                                                                                                                                                                                                       | Yes. New devices and concepts are emerging                                                                                                                                                                                                                                                                                                                                                                          |

|  |                                                                                                                                                                                                |  |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|
|  | <p>if applicable, to devices involved in the procedure?</p> <p>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?</p> |  |
|--|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--|

### Current management

|   |                                                                                                                                                                                                                                                       |                                                                                                                                                     |
|---|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------|
| 6 | 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 or bridge to transplant or decision |
| 7 | <p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p> | ECMO is another procedure, different device, different concept and different approach                                                               |

## Potential patient benefits and impact on the health system

|    |                                                                                                                                                                                                                                                   |                                                                                                                                 |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------|
| 8  | What do you consider to be the potential benefits to patients from using this procedure/technology?                                                                                                                                               | life saving, extend the time awaiting for heart transplant, safer procedure in high risk patients, amongst other indications... |
| 9  | Are there any groups of patients who would particularly benefit from using this procedure/technology?                                                                                                                                             | Cardiogenic shock patients                                                                                                      |
| 10 | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br><br>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                           |
| 11 | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?                                                                                                                                   | Well equipped cath labs, ICUs and well trained staff in ICU, theatres and cardiology wards                                      |
| 12 | 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

|    |                                                                                                                                                                                    |                                                                          |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|
| 13 | What are the potential harms of the procedure/technology?<br><br>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: | Aortic valve injury<br>Bleeding<br>Stroke<br>Haemolysis<br>Limb ischemia |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------|

|           |                                                                                                                                                                                  |                                                                                                                                                                  |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|           | <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p> | <p>Thrombocytopenia</p> <p>Vascular injury</p> <p>Renal dysfunction</p>                                                                                          |
| <b>14</b> | 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                                  |
| <b>15</b> | Please list any uncertainties or concerns about the efficacy and safety of this procedure/?                                                                                      | 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 |
| <b>16</b> | Is there controversy, or important uncertainty, about any aspect of the procedure/technology?                                                                                    | There is always controversial points                                                                                                                             |
| <b>17</b> | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):                                                                       | A minority of hospitals, but at least 10 in the UK.                                                                                                              |

### Abstracts and ongoing studies

|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |              |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|
| <b>18</b> | <p>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).</p> <p>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</p> | DanGer trial |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------|



### Further comments

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

## Declarations of interests

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

| Type of interest *                | Description of interest                                                                        | Relevant dates |                 |
|-----------------------------------|------------------------------------------------------------------------------------------------|----------------|-----------------|
|                                   |                                                                                                | Interest arose | Interest ceased |
| <i>Non-financial professional</i> | I am involved in the national working group for Emergency guidelines publication on the device | 2024/2025      |                 |
| Choose an item.                   |                                                                                                |                |                 |
| Choose an item.                   |                                                                                                |                |                 |

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

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

|             |                     |
|-------------|---------------------|
| Print name: | ( Mostafa ElAdawy ) |
| Dated:      | ( 04/06/2025 )      |

## Professional Expert Questionnaire

**Technology/Procedure name & indication:**

### Your information

|                                                                     |                                                                                                                                          |
|---------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|
| <b>Name:</b>                                                        | <input type="text" value="Waqas Akhtar"/>                                                                                                |
| <b>Job title:</b>                                                   | <input type="text" value="Consultant"/>                                                                                                  |
| <b>Organisation:</b>                                                | <input type="text" value="Guy's &amp; St Thomas' NHS Trust"/>                                                                            |
| <b>Email address:</b>                                               | <input type="text" value=""/>                                                                                                            |
| <b>Professional organisation or society membership/affiliation:</b> | <input type="text" value="Previous 24/25 Council of Academy of Medical Royal Colleges and Board of Faculty of Intensive Care Medicine"/> |
| <b>Nominated/ratified by (if applicable):</b>                       | <input type="text" value="Click here to enter text."/>                                                                                   |
| <b>Registration number (e.g. GMC, NMC, HCPC)</b>                    | <input type="text" value="7073628"/>                                                                                                     |

### How NICE will use this information:

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

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

Your advice and views represent your individual opinion and not that of your employer, professional society or a consensus view. Your name, job title, organisation and your responses, along with your declared interests will also be published online on the NICE website as part of public

consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

**For more information about how we process your data please see [our privacy notice](#).**



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

 Click here to enter text. 

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

|   |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 |                                                                                                                                                                                                                                                                                                                                                                             |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1 | <p>Please describe your level of experience with the procedure/technology, for example:</p> <p>Are you familiar with the procedure/technology?</p> <p>Have you used it or are you currently using it?</p> <ul style="list-style-type: none"><li>– Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?</li><li>– Is this procedure/technology performed/used by clinicians in specialities other than your own?</li></ul> | <p>Work with Impella CP and 5.5 on a daily basis in both my roles as a consultant in Intensive Care and Cardiology (subspecialty of advance heart failure, transplantation and mechanical circulatory support).</p> <p>The use of these devices is limited to a few centres across the country with very little overall experience outside of heart transplant centres.</p> |
|---|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|   |                                                                                                                                                                                                                                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                   |
|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | <ul style="list-style-type: none"> <li>- If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.</li> </ul>                                                                                                                                                                                                    |                                                                                                                                                                                                                                                                                                                   |
| 2 | <ul style="list-style-type: none"> <li>- Please indicate your research experience relating to this procedure (please choose one or more if relevant):</li> </ul>                                                                                                                                                                                                                                                   | I have done bibliographic research on this procedure.                                                                                                                                                                                                                                                             |
| 3 | <p>Does the title adequately reflect the procedure?</p> <p>Is the proposed indication appropriate? If not, please explain.</p> <p>Does this have a multi-indication?</p> <p>How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design?</p> <p>Which of the following best describes the procedure (please choose one):</p> | <p>Yes</p> <p>Yes but there can be some subdivisions in the multiple indications – eg below:</p> <p>Impella CP for cardiogenic shock<br/>Impella CP for unloading in ECMO<br/>Impella 5.5 as bridge to heart transplantation</p> <p>It is a very novel approach</p> <p>The first in a new class of procedure.</p> |
| 4 | Does this procedure/technology have the potential to replace current standard care or                                                                                                                                                                                                                                                                                                                              | Yes certainly with the DangerSHOCK trial it should replace current practice (eg IABP). For Impella 5.5 bridge to transplant it is an effective tool to add to current options.                                                                                                                                    |

|          |                                                                                                                                                                                                                                                                             |                                                                                                                                                                                 |
|----------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|          | would it be used as an addition to existing standard care?                                                                                                                                                                                                                  |                                                                                                                                                                                 |
| <b>5</b> | <p>Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?</p> <p>Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?</p> | <p>This is the first such guidance as I understand</p> <p>There has been the recent publication of the DangerShock trial which has significantly changed the evidence base.</p> |

### Current management

|          |                                                                                                                                                                                                                                                       |                                                                                                                                                                                                                                                                                      |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>6</b> | Please describe the current standard of care that is used in the NHS.                                                                                                                                                                                 | This is a postcode lottery. In some centres it would be vasoactive medications and maybe a intra-aortic balloon pump. In other places there has been option for using ECMO and other mechanical circulatory support devices (eg transplant centres)                                  |
| <b>7</b> | <p>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?</p> <p>If so, how do these differ from the procedure/technology described in the briefing?</p> | <p>Not directly to this device. However there are many forms of mechanical circulatory support eg ECMO, BiVADs, LVADs</p> <p>This is a unique form of short term support that offers effective unloading without need for sternotomy and has evidence base unlike other devices.</p> |

## Potential patient benefits and impact on the health system

|    |                                                                                                                                                                                                                                                   |                                                                                                                                                                                                                                        |
|----|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 8  | What do you consider to be the potential benefits to patients from using this procedure/technology?                                                                                                                                               | The NNT of 8 to prevent 1 death in post infarct cardiogenic shock with an Impella CP is a benefit where no other intervention other than PCI has shown effectiveness.                                                                  |
| 9  | Are there any groups of patients who would particularly benefit from using this procedure/technology?                                                                                                                                             | Post myocardial infarct cardiogenic shock.                                                                                                                                                                                             |
| 10 | Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system?<br><br>Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment? | Yes as above with the DangerShock trial with significant mortality benefit.<br><br>Impella 5.5 allows effective bridging to heart transplantation without need for sternotomy which reduces time for recovery and listing.             |
| 11 | What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?                                                                                                                                   | There is needs to be a network approach to concentrate delivery of these devices to experienced centres as the subsequent management is key and sufficient volume needs to occur to allow all involved to become effective in its use. |
| 12 | Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?                                                                                                                                      | Yes there must be established training for all staff groups including a focus on troubleshooting and resuscitation training as these devices alter advanced life support algorithms and carry a high risk of complications.            |

## Safety and efficacy of the procedure/technology

|    |                                                                                                                                                                                    |                                                                                                                                                                                                        |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 13 | What are the potential harms of the procedure/technology?<br><br>Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: | The NNT to harm is 5 with increased number of a range of bleeding/vascular access/renal injury issues. Therefore need good level of training and volume experience for this to be as safe as possible. |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

|           |                                                                                                                                                                                  |                                                                                                              |
|-----------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------|
|           | <p>Adverse events reported in the literature (if possible, please cite literature)</p> <p>Anecdotal adverse events (known from experience)</p> <p>Theoretical adverse events</p> |                                                                                                              |
| <b>14</b> | Please list the key efficacy outcomes for this procedure/technology?                                                                                                             | Mortality                                                                                                    |
| <b>15</b> | Please list any uncertainties or concerns about the efficacy and safety of this procedure/?                                                                                      | Utilisation of Impella outside of cardiogenic shock post myocardial infarct and as bridge to transplantation |
| <b>16</b> | Is there controversy, or important uncertainty, about any aspect of the procedure/technology?                                                                                    | Utilisation of Impella outside of cardiogenic shock post myocardial infarct and as bridge to transplantation |
| <b>17</b> | If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):                                                                       | Would need to be high volume PCI and transplant centres 50-60 in country.                                    |

### Abstracts and ongoing studies

|           |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                                                                                        |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
| <b>18</b> | <p>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).</p> <p>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</p> | <p>The most important here is the DangerShock trial which was also performed at our hospital in Harefield, London.</p> |
|-----------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|

|    |                                                                                                                  |                                                                                                                        |
|----|------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------|
|    | us if you list any that you think are particularly important.                                                    |                                                                                                                        |
| 19 | Are there any major trials or registries of this procedure/technology currently in progress? If so, please list. | Yes many outstanding <a href="https://pubmed.ncbi.nlm.nih.gov/37926367/">https://pubmed.ncbi.nlm.nih.gov/37926367/</a> |
| 20 | Please list any other data (published and/or unpublished) that you would like to share.                          |                                                                                                                        |

### Other considerations

|    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |                                                                                                                                                                                                                                  |
|----|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 21 | Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?                                                                                                                                                                                                                                                                                                                                                                                                                    | ~1000+                                                                                                                                                                                                                           |
| 22 | <p>Please suggest potential audit criteria for this procedure/technology. If known, please describe:</p> <ul style="list-style-type: none"> <li>– 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.</li> <li>– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:</li> </ul> | <p>Beneficial outcome measures:</p> <p>Mortality</p> <p>LOS on intensive care and ward</p> <p>Functional outcomes</p><br><p>Adverse outcome measures:</p> <p>Bleeding</p> <p>Vascular access damage</p> <p>Renal replacement</p> |

## Further comments

|    |                                                                                                                                  |                                                                                                                                                                                                                                                                                                                      |
|----|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 23 | If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe. | Impella has a important place in the management of cardiogenic shock however this is much more about the system than the device itself and there needs to a be a coordinated approach to the equitable delivery, transfer, indications, subsequent management and explanation of the device for it to be successful. |
|----|----------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|

## Declarations of interests

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

| Type of interest *        | Description of interest       | Relevant dates |                 |
|---------------------------|-------------------------------|----------------|-----------------|
|                           |                               | Interest arose | Interest ceased |
| <i>Direct - financial</i> | Honoraria Speaker Abiomed/J&J | 2023           | ongoing         |
| Choose an item.           |                               |                |                 |
| Choose an item.           |                               |                |                 |

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

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

|             |                                           |
|-------------|-------------------------------------------|
| Print name: | <input type="text" value="Waqas Akhtar"/> |
| Dated:      | <input type="text" value="25/6/25"/>      |