View results

Respondent

64 Anonymous

64:41
Time to complete

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

IP1071/2

Your information

2. Name: *

Chris Harvey

3. Job title: *

ECMO Director

4. Organisation: *

University Hospital of Leicester

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

MRCS Glasgow

7. Nominated/ratified by (if applicable):

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

GMC 4320014

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, as communicated by the coordinator/administrator.

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

(●) I agree

( ) I do not agree

How NICE will use this information:

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

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with your declared interests will also be published online on the NICE website as part of public consultation on the draft guidance, except in circumstances but not limited to, where comments are considered voluminous, or publication would be unlawful or inappropriate.

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

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

(●) I agree

( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

I have been caring for patients and adults on ECMO since 2001. I have experience of managing both adults and children with cardiac and respiratory disease requiring ECMO. I am well placed to assess the technology as my surgical background gives me detailed knowledge of cannulation technique. As my role is solely in the care of the ECMO patients i have a through knowledge of the technical side of ECMO technology and have been consulted by industry in the past on pump, oxygenator and cannula design.

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.

There has been a marked increase in the demand for cardiac support globally. Where ECMO was largely confined to cardiac surgery and intensive care there has been a move internationally to involve specialities such as cardiology and emergency medicine

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).
- [x] I have done clinical research on this procedure involving patients or healthy volunteers.
- [ ] I have published this research.
- [ ] I have had no involvement in research on this procedure.
- [ ] Other

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

The indication of acute cardiac failure is diverse and given the fact that the outcomes from say ECMO for cardiac arrest and post cardiotomy ECMO are vastly different for support for acute viral myocarditis a more focused definition may be required as to which sub groups this guidance is attributable to

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

The basic ECMO equipment (pump and oxygenator) are not new and the technology is fairly standard across all equipment manufactures. What has changed recently is the number of devices that are available and the widening of the indication to offer support. During COVID NHSE conducted a servey nationally looking that the number of ECMO machines that were available around the country and if my memory is correct this is around 300 (approximately 200 levotronix centrimag and the remainder cardiohelp)

17. 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.

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

The management of acute heart failure needs to be multi-faceted and should encompass a combination of drug therapy, cardiological interventions (catheter and electrophysiological) as well as mechanical circulatory support (ECMO, Impella and IABP)

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

Widening of indication with increased usage in more centers but fundamentally the ECMO equipment and management has changed little in the last 20 years

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Evidence base is broadening with marked variation in outcome based on the indication

21. Do you think the guidance needs updating?

yes

Current management

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

First line is inotropic management +/- revascularization

Mechanical circulatory support in the form of ECMO is provided only in larger (usually respiratory ECMO centers). I am aware of a number of patients in whom ECMO has been commenced my clinicians with limited or no experience of ECMO support and once commenced the panic button is pressed. In my experience this usually leads to a bad outcome.

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

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

ECMO is the most adaptive short term support and as indicated in the introduction provides cardiac and respiratory support. Other modalities capable of providing some circulatory support include the Abiomed Impella and the Intra-aortic ballon pump (IABP)

Potential patient benefits and impact on the health system

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

Improved survival with intact neurology

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

Younger patients with non-ischemic cardiac disease e.g. acute viral myocarditis or post-partum cardiomyopathy

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?

    Potential to improve outcome but it in itself is a highly invasive and potentially complex high risk intervention

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

    The technology would be best managed in a small number of high volume centers based around a hub and spoke model with patients being commenced on ECMO by the expert team or cannulated locally then retrieved with mobile ECMO. Centers caring for these patients must have cardiac surgery and cardiology on site in addition to a dedicated ITU team.

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

    Yes. A detail knowledge of the management of the ECMO circuit and any complications that may present during the run would be essential

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

    Unless the underlying cause for the heart failure has been addressed or is time limiting then ECMO would be futile. The main risk from ECMO support include hemorrhage (especially intra cerebral) and critical limb ischaemia (from arterial cannulation).
    There would also need to consider the pathway in those patients who survive but remain dependent on ECMO and the potential need for long term mechanical assist +/- transplant in a time where there are already shortages of organs

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

    % survival with intact or minimal neurological sequalae

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

    Extra-corporeal cardiac arrest (ECPR) especially in the out of hospital arrest group may be difficult. There is now randomised evidence of improved outcomes but this is only in highly select patients, in the best prognostic groups and when the procedures are performed by highly designated teams.

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

    Potential uncertainty in whom has greatest benefit and when ECMO would be deemed futile

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

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

Abstracts and ongoing studies

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

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

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

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

Other considerations

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

    Difficult to say depending on how wide the population included. If you included non ischaemic patients in whom the best outcomes would be achieved then the numbers would be relatively small <50 per year across the uk. If however the population of ischaemic patients/ cardiac arrest patients are included then the numbers could rapidly become prohibitive and the survival would be around 30% at best with high attrition rate.

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.

    Separation from ECMO at 10 days
    Discharge from the ITU alive
    Survival at 30 AND 180 days post discharge

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:

Neurological performance score at 30 and 180 days
No evidence of limb ischaemia at discharge
Need for long term circulatory support/VAD

Further comments

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

With increased usage the groups at most benefit are being more refined.
As stated already there needs to be strictly applied criteria as to whom is offered support and a tightly defined time frame in which support may be offered.
Once there is evidence of established end organ damage through a low cardiac output state then ECMO would be highly unlikely to improve outcome.
The duration of support would also need defining as again support longer than 10 days (unless accepted on a VAD/transplant program) is unlikely to yield significant clinical benefit.

Declarations of interests

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

41. Type of interest: *

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

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

I have been paid an honorarium of £500 by Medtronic to lecture on the use of the Crescent Dual Lumen ECMO cannula in the management of adult respiratory failure

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: *

Chris Harvey

45. Date: *

03/10/2024

View results

Respondent

65 Anonymous

15:02
Time to complete

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

Miguel Garcia

Your information

2. Name: *

Miguel Garcia

3. Job title: *

Consultant Anesthetists and Intensive care

4. Organisation: *

Wythenshawe Hospital

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

FRCA FFCIM

7. Nominated/ratified by (if applicable):

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

6061793

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, as communicated by the coordinator/administrator.

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- (●) I agree
- ( ) I do not agree

How NICE will use this information:

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

Yes

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

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

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

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

I am the ECMO Director for Wythenshawe Hospital, actively involved in the deployment of veno-arterial ECMO. I regularly use this technology in the context of ECMO CPR, bridge to recovery, decision-making, or transplant. In the North-West, ECMO is primarily used by another centre, mainly for post-cardiotomy ECMO. I understand that this technology is more widespread in London, with several specialties involved, including cardiac surgeons and intensivists.

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

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

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

yes

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

ECMO has been in use for many years, and new technologies like the Impella device offer additional options for heart failure management. However, research into its long-term efficacy as a bridge to solutions like transplants is ongoing and inconclusive

17. 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.

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

ECMO holds the potential to replace current standards of care, especially for conditions such as drug overdose, pulmonary embolism, and cardiac arrest, where no definitive pathways to access such technologies currently exist.

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

No

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

No

21. Do you think the guidance needs updating?

yes

Current management

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

I general intensive care

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?

There have been no substantial modifications to the ECMO technology in recent years, nor significant changes in its safety or efficacy. Currently, veno-arterial ECMO is used as a bridge to recovery, decision-making, or transplant in transplant centers. Impella devices, available in some centers, may serve as an alternative to ECMO for certain patients with treatable pathologies, such as acute cardiomyopathy, pulmonary embolism, or drug overdoses.

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?

Pulmonary embolism, Overdose, refractory VF, electrical storm and hypothermia

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

Pulmonary embolism, Overdose, refractory VF, electrical storm and hypothermia

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?

    While ECMO has the potential to improve outcomes, especially in the context of acute, reversible conditions, it also requires adequate provision of intensive care beds and a commissioned retrieval service. If not applied correctly, it can lead to harm, resource strain, and increased patient suffering. Therefore, further studies should be conducted to establish clear protocols for using ECMO in cases like drug overdose and cardiac failure to ensure its effectiveness and safety.

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

    bed capacity

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

    ECMO center training

Safety and efficacy of the procedure/technology

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

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

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

    Inadequate selection, increasing suffering. Ischemic legs and dead

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

    As bridge to LVADS and transplant > 80 %

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

    No evidence in cardiac arrest
    Yes not RCT conclusive

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

    evidence for CPR

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.

    NA

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

    ELSO

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

    NA

Other considerations

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

    30-60 in the north west

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.

    Beneficial outcome measures: Mortality LOS use blood products disability

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:

    Dead Ischaemic events neurological

Further comments

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

NA

Declarations of interests

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

41. Type of interest: *

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

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

NA

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: *

Miguel Garcia

45. Date: *

15/10/2024

View results

Respondent

66 Anonymous

26:59
Time to complete

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

IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

2. Name: *

Nicholas Barrett

3. Job title: *

Clinical Director and Consultant in Intensive Care Medicine

4. Organisation: *

Guy's and St Thomas'm NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

EuroELSO

7. Nominated/ratified by (if applicable):

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

4677156

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, as communicated by the coordinator/administrator.

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- (●) I agree
- ( ) I do not agree

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

- (●) I agree
- ( ) I disagree

The procedure/technology

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

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

Are you familiar with the procedure/technology?

Yes, I use the technology as part of my routine clinical practice

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 am currently using this equipment. The technology is used in specialist centres including those providing the severe respiratory service and in heart/lung transplant centres. I am involved directly un the selection, commencement and management of patients on VA ECMO. Other specialties involved include cardiac surgery and cardiology

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

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

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

Yes, but it could be further refined with a separation into ischaemic and non-ischaemic acute heart failure

16. 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 used currently within the NHS but is not considered standard of care due to a lack of evidence supporting its use

17. 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.

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

Yes, it would be an addition

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

No

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

Yes, the evidence for the use of VA ECMO in ischaemic heart disease is poor and demonstrates no significant benefit. However there is evidence - mainly observational - that outcomes in patients with non-ischaemic pathology, eg drug overdose, myocarditis and acute cardiomyopathies do very well with limited impact on heart failure/transplant services in the long term

21. Do you think the guidance needs updating?

Yes - separation of ischaemic and non-ischaemic pathology

Current management

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

At present patients are managed medically with inotropic medications in an ICU setting. These patients have a very high mortality (>50%)

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

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

Not directly although other devices including the impella and intra-aortic balloon pump are short term mechanical support devices and VADs are medium/long term support devices for this population

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?

For a small segment of patients, an improvement in survival

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

Yes - patients with non-ischaemic acute cardiogenic shock (eg medication overdose, viral myocarditis, peripartum cardiomyopathy, autoimmune/vasculitic myocarditis)

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

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

    Yes - it could lead to improved outcomes

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

    The technology needs to be deployed in a tertiary intensive care unit with the ability to provide inter-hospital transfer and with access to all relevant specialties including cardiac surgery, cardiology, heart failure, vascular surgery as well as imaging, laboratories, transfusion, theatres

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

    yes. There needs to be significant training of the multidisciplinary team to allow the technology to be used safely and to ensure that complications are minimised. For this reason existing centres should be prioritised and where new centres are identified, a process of education and ongoing mentoring should be put in place.

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

    Bleeding into any body cavity including intracranial, thrombosis of major vessels, multiple organ failure

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

    death
    the length of
    ICU stay
    acute renal failure warranting renal-
    replacement therapy
    recurrent myocardial infarction
    rehospitalization for congestive heart failure
    neurologic outcome
    bleeding
    stroke
    systemic embolization,
    peripheral ischemic vascular complications

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

    concerns about efficacy in the myocardial infarct pupulation with trials showing negative results.

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

    Yes - efficacy in myocardial ischaemia

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

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

Abstracts and ongoing studies

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

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

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

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

Other considerations

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

    nationally, if restricted to a population with non-ischaemic heart failure in cardiogenic shock <150

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

    Beneficial outcome measures.

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

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

Adverse outcome measures.

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

Further comments

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

further research is definitely required. The difficulty is that the population with non-ischaemic heart failure have diverse pathologies and are relatively rare. It is difficult to see trials being operformed in this population due to the rarity and lack of equipoise in clinicians

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
- [x] 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. *

Ex president of EuroELSO and ongoing board member (2014-current) and research funding - paid to institution, no personal financial conflict (2015-current)

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: *

nicholas barrett

45. Date: *

19/10/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

Name:	Dr Owais Dar
Job title:	Consultant Cardiologist in Heart Failure, Transplant & Mechanical Circulatory Support
Organisation:	Harefield Hospital (a division of Guys and St Thomas' NHS foundation Trust)
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Society for Heart Failure, European Society of Cardiology, Heart Failure Association of the European Society of Cardiology
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4721206

How NICE will use this information:

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

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	Yes I am familiar with the technology and its use. My unit implants VA ECMO and we are a centre to which other centres refer for this therapy. I have worked as a consultant for 9 years as a mechanical circulatory support (includes VA ECMO) and transplant cardiologist working in an Internationally recognised advanced heart failure unit focused on heart failure, transplantation and LVAD therapies. I have obtained my research degree from National Heart and Lung Institute, Imperial College London, studying the role of telemonitoring in heart failure patients. I have completed my cardiology subspecialist training in The Royal Brompton and Harefield Hospitals NHS Trust, Vienna General Hospital, Stanford Health Care. I am an adjunct senior lecturer at the school of cardiovascular medicine & sciences Kings College London. I am a director of an international course dedicated to spreading knowledge and skills related to advanced heart failure transplantation and mechanical circulatory support.
	Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the	Yes I work in an advanced heart failure service which is actively using VA ECMO Yes I do know or can estimate.

	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 VA ECMO is used by intensivists and cardiac surgeons - I am involved in patient selection and decision making. As a advanced heart failure cardiologist I take referrals from other centres with patients in cardiogenic shock who need work up for transplant or LVAD. I make decisions about who needs and gets VA ECMO or other therapies eg Impella, Centrimag, durable LAVD, or transplant, or palliative care
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	Other (please comment): I have done my MDres degree on heart failure research at Imperial College London. I am an Honorary Senior Lecturer, Adjunct Senior Lecturer at the School of Cardiovascular Medicine & Sciences Kings College London. I am supervising 4 MD/ PhD fellows and am conducting research on advanced heart failure, cardiogenic shock, heart transplantation and mechanical circulatory support.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes – I would consider using the term advanced heart failure or shock rather than acute heart failure I would say VA ECMO for acute cardiogenic shock rather than acute heart failure. Acute heart failure can be mild whilst cardiogenic shock is more severe and better reflects the need for VA ECMO I think it is the standard of care for those failing inotropic therapy Established practice and no longer new.

4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Used in addition to current standard of care – ie in addition to inotropes
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	N/A this is a relatively new procedure and the implantation technique is either surgical cut down or percutaneous implantation.

Current management

6	Please describe the current standard of care that is used in the NHS.	Inotrope therapy is the standard of care as first line therapy for cardiogenic shock. VA ECMO is becoming the standard of care for managing patients in shock who are failing inotropic therapy. Impella has also become a standard of care for patients in cardiogenic shock.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Impella devices (cp and 5.5), Intra aortic balloon pumps, centrimag levotronix devices, inotropes The mode of function is completely different to ECMO Impella: per cutaneous vascular device

		IABP – per cutaneous vascular device Centrimag – open heart surgery Inotropes – medication intravenous

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?	VA ECMO can be used as a bridge to recovery, decision, heart transplant or LVAD therapy, peri cardiac arrest. It's likely to improve survival and quality of life.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Cardiogenic shock due to myocarditis – 90% recover to go home on tablet therapy Young people in cardiogenic shock who would be eligible for heart transplant or LVAD therapy
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes Yes (it's a difficult question to answer because without this treatment patients would die. Those who wont get ECMO will likely die. Dead patients wont be readmitted. If ECMO saves their life it will mean they will be readmitted in the future.)
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	You need trained operators, cath lab team, ITU team, perfusionists, ideally done in a unit with a cardiothoracic surgical service
12	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

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	VA ECMO – During implantation – vascular access damage

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Infection, bleeding, thrombosis (ischaemic leg, stroke etc.), worsening pulmonary oedema, haemolysis leading to renal failure Richardson, Alexander. Extracorporeal Cardiopulmonary Resuscitation in Adults. Interim Guideline Consensus Statement From the Extracorporeal Life Support Organization. *ASAIO Journal* 67(3):p 221-228, March 2021. | *DOI:* 10.1097/MAT.0000000000001344
14	Please list the key efficacy outcomes for this procedure/technology?	Survival, survival to discharge from hospital, adverse events
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Typically VA ECMO gives you a 2 week period to bridge the patient to recovery, transplant, LVAD or a mid-term mechanical circulatory support device such as Centrimag. Beyond 4 weeks the complication rates are very high.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Not to my knowledge. There is debate about which therapy (ECMO or Impella is better)
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK.
18	Are people who are pregnant or have recently been pregnant eligible for VA ECMO for acute heart failure?	Yes but with serious limitations

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this	Nil new as per the question

	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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Extracorporeal Life Support Organization ELSO Registry | ECMO | Extracorporeal Membrane Oxygenation
21	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

22	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)?	Acute cardiogenic shock (NOT post surgical) >1000 people
23	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	Beneficial outcome measures: Survival to discharge from hospital Survival overall Quality of life at discharge and 1 year Percentage of people who return to work

	appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: Pulmonary oedema, Vascular access damage (bleeding, dissection, ischaemic limb, thrombosis) Stroke Haemolysis Infection Renal failure

Further comments

24	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	We need to do a randomised controlled trial (RCT) for the use of VA ECMO in patients not suitable for transplant or LVAD (most likely due to age) to see if such patients would benefit form VA ECMO. We should consider RCTs in specific groups Eg. Post cardiotomy, post primary PCI, acute fulminant myocarditis, DCM phenotype, those aged 65 -80.

NICE National Institute for Health and Care Excellence

Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	I have received educational grants and research grants from Abbott. I am also on Abbotts structural heart clinical advisory group	**Over the last 2 years**	**ongoing**
Direct - financial	I have a consultancy agreement with Acorai AB which is a startup company who are developing a non-invasive cardiac output monitor device	**Over the past 2 years**	**ongoing**
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:	**Owais Dar**
Dated:	**25/10/2024**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

Name:	Click here to enter text. Dr Sachin Shah
Job title:	Click here to enter text. Consultant in Critical Care & lead for mechanical circulatory support service
Organisation:	Click here to enter text. Barts Health NHS Trust
Email address:	Click here to enter text. [redacted]
Professional organisation or society membership/affiliation:	Click here to enter text. FRCA, FFICM, EDIC
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text. GMC: 6030345

How NICE will use this information:

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

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own?	I have used this technology in my clinical practice for over 15 years. I currently work in one of the largest users of the technology at Barts Heart Centre. Including my fellowship Harefield Hospital (UKNHSBT transplant centre). I have been involved in the care of over 400 patients who have received this technology. I have been involved in setting up the Extracorporeal Membrane Oxygenation (ECMO) at St. Bartholomew's Hospital, Barts Health NHS Trust since 2016. I have led this service since January 2020 especially during the time of pandaemic. I lead the ECMO service in the largest cardiogenic shock network in the UK, providing for a catchment area of 3.5 million people across 9 referral hospitals into Barts Heart Centre. We support around 50 patients per annum with this technology and receive around 100 referrals for it per annum. I have published on ECMO and extra-corporeal CPR (E-CPR). I have been invited multiple times internationally to deliver lectures on this topic.

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have recruited patients for research. Other (please comment)
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	No. I think Cardiogenic Shock instead of acute heart failure is a better title. Cardiogenic shock is the most extreme manifestation of acute heart failure and is the indication for the technology. There will be thousands of patients admitted with acute heart failure per annum in the UK, a large majority of them will receive conventional management as per current standards. Only a small proportion will need the technology due to progression to cardiogenic shock. This technology is currently embedded in limited sites with the capability as standard of care for eligible patients with cardiogenic shock. The technology has been available in various iterations for over 30 years. Whilst there have been advances in cannulae, circuitry, oxygenators and pump heads, there has only been modest innovation in the technology over the last decade.
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?	No. Due to complications and a limited evidence base, it is only suitable for a small proportion of patients (approximately 10%) with cardiogenic shock – notably those who are refractory to optimal medical management.

5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	See above There has been several randomised control trials and single centre case series, see below.

Current management

6	Please describe the current standard of care that is used in the NHS.	Current standard of care is best supportive care using fluid resuscitation, inopressors, intra-aortic balloon pump, and either the Impella device or VA ECMO in the most severe or refractory cases.VA ECMO for most refractory cases is only available at the limited centres within UK. This includes 6 regional advanced heart failure centres and 8 national severe acute respiratory failure (SARF) centres. Currently there are no nationally agreed criteria for VA ECMO nor are there any defined pathways of care or referral for patients. This results in heterogenous and inequitable provision and delivery of VA ECMO nationally. All decisions regarding use of this technology including risk/benefit, bridging strategy, timing and management should ideally be made in consultation with multidisciplinary expertise including but not limited to (advanced) heart failure, other relevant cardiology specialties (intervention, electrophysiology, adult congenital

		heart diseases), intensive care / cardiac intensive care, nursing, perfusion.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	The Impella Device (J&J MedTech) is a transvalvular microaxial flow pump which provides support for the left ventricle without oxygenation. It is a family of devices, the most common of which provide either 3.5L or 5.5L of blood flow. It requires fluoroscopy for insertion via 14F femoral access in the catheter lab or via surgical cut down. Recent data (doi: 10.1056/NEJMoa2312572) support its use in select patients with ST elevation MI and cardiogenic shock with predominant left ventricular failure, low ejection fraction and a low likelihood of neurological injury from cardiac arrest. This pump differs from VA ECMO in its mode of action (microaxial flow vs centrifugal), univentricular support (vs biventricular) and inability to oxygenate blood.

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?	Restoration of vital organ perfusion in more severe forms of cardiogenic shock which may be potentially lifesaving, particularly in aetiologies (see below) of cardiogenic shock where there is a high probability of cardiac recovery to allow weaning and removal of the technology over a period of days or a pre-defined route towards heart replacement therapies has been identified in consultation with advanced heart failure centres.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Bridge to cardiac transplantation in eligible patients, specifically those with decompensated (known) cardiomyopathy who have been listed for transplantation Select patients with potentially reversible SCAI Stage D or E Cardiogenic shock as a bridge to recovery with suspected or proven myocarditis, drug overdose, hypothermia, peripartum cardiomyopathy, refractory arrythmia, graft failure post cardiac transplantation, select cases with sepsis and cardiac dysfunction, acute myocardial infarction, pulmonary embolism, following cardiac surgery Refractory cardiac arrest with high likelihood of good neurological outcome (Extracorporeal CPR)
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	There are currently no defined pathways of care for VA ECMO and no national level audit data to understand its use, patient outcomes and costs to the NHS. This almost certainly results in heterogenous care and outcomes nationally as well and inequity of access. Notably, this exists for cardiogenic shock as well. As outlined in the Shock to Survival framework document (https://ics.ac.uk/resource/shock-to-survival-report.html) it is conceivable that organisation of regionalised pathways for cardiogenic shock would improve equity of access to optimal and best care including the use of VA ECMO and hence patient outcomes. Recommendations to support commissioning of a national VA ECMO service which parallel

		many of the successes of the commissioning of VV ECMO (SARF) would provide a more structured, governed and equitable service nationally which would in turn likely lead to better resource utilisation and outcomes which would be measured through ICNARC data collection and reviewed at structured national meetings supported by NHSE and specialist commissioners.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	A national agenda (supported by relevant societies BCIS, BCS and ICS) to improve and embed the early recognition and escalation of patients with cardiogenic shock including greater equity of access to diagnostic tests, specifically point of care cardiac ultrasound. Formation of regional cardiogenic shock networks with clear, 24/7, referral pathways to regional shock centres with the capability to support patients with all severities of cardiogenic shock including those requiring VA ECMO. In addition, shock centres would provide the capability to retrieve those patients on VA ECMO who cannot be moved via conventional methods. See: https://ics.ac.uk/resource/shock-to-survival-report.html Equitable access to experts in cardiogenic shock and the use of mechanical circulatory support technologies through a regionalised, single point of contact MDT as outlined above. An agreed set of standards and national service specification for (shock) centres that care for patients with both cardiogenic shock and VA ECMO. Capability for both univentricular and biventricular short- term MCS devices as a bridge to decision, bridge to advanced heart failure treatment and as a bridge to long-term MCS to assess transplant candidacy Shock centres which work closely with supra-regional AHFCs, where not co-located, to ensure all patients with CS who might benefit from a heart transplant are discussed Support education and training in the awareness, recognition and management of cardiogenic shock from shock centres across their geographical network with and embedding of locally approved escalation protocols across the network A network governance structure to support audit, quality improvement and bi-directional learning across the network A nationally agreed core outcomes data set embedded into national audit.

12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	The technical aspect of the training (i.e cannulation) can be extrapolated from existing VVECMO services. There are other aspects of training which needs to consider. The causes of cardiogenic shock are varied and the associated complications of cardiogenic shock may be multisystem. Cardiogenic shock patients therefore need access to wider specialist services including but not limited to vascular surgery, interventional radiology, neurology and obstetrics. In patients who do survive, their stay in critical care can be prolonged and allied health specialty input is crucial to recovery. The poor survival rates for cardiogenic shock and patients supported with VA ECMO calls for specialist palliative care services to support both patients and their families. For those who survive, the burden of heart failure is significant requiring access to heart failure services, specifically heart failure nurse specialists and cardiac rehabilitation. Psychiatric disease and psychological distress are common. In essence, a team of teams is required across the patient pathway to improve outcomes and ensure best care.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Some harms are associated with the underlying condition (cardiogenic shock) and some with the technology itself Stroke: Ischaemic 3.9%, haemorrhagic 2.9% Bleeding: 30% Limb ischaemia: 10% Infection: 16% Haemolysis: Liver Injury: 27% Acute Kidney injury: 50% with need for renal replacement in 20% Mesenteric Ischaemia: 9%

14	Please list the key efficacy outcomes for this procedure/technology?	Mortality: In-hospital, 30d, 180d and 1 year survival
		ICU & Hospital length of stay
		Organ support days (respiratory, cardiac and renal)
		Cause of death: Cardiovascular, non-cardiovascular, undetermined
		Safety events:
		• CNS Injury: All stroke, Symptomatic hypoxic-ischemic injury, Covert CNS infarction or haemorrhage, Neurologic dysfunction (acutely symptomatic) without CNS injury
		• Bleeding events: VARC 1-5
		• Vascular and Structural cardiac complication
		  ○ Major
		  ○ Minor
		• Access related non-vascular complications
		  ○ Major
		  ○ Minor
		• Bleeding VARC classification 1-5
		• Organ System Dysfunction
		  ○ Hepatic dysfunction/Liver Injury
		  ○ Acute Kidney Injury
		  ○ Mesenteric Ischemia
		  ○ Pulmonary Haemorrhage
		  ○ Refractory Pulmonary oedema
		• Haematological events
		  ○ Haemolysis
		  ○ Thrombocytopenia
		  ○ Infection
		  ○ Percutaneous insertion site infection
		  ○ Blood stream infection
		  ○ Sepsis Device Malfunction
		• General Device Malfunction
		  ○ Device Thrombus
		  ○ Accidental Decannulation/Device Cannula Migration
		• Vascular & cardiac structural complications
		  ○ Major
		  ○ Minor

		HRQoL: Euro-QOL-5D-5L, Lawton Instrumental Activities of Daily Living, modified Rankin scale Hospital-free days Hospitalizations: all cause, cardiovascular, heart failure related, non-cardiovascular, undetermined Cost: QALY

15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Numerous uncertainties remain in terms of management
		○ Optimal management strategies on VA ECMO: target oxygenation, target ventilation, target anticoagulation, optimal blood flow, target MAP, use of inopressors, monitoring, minimisation of complications including routine use of a distal leg perfusion cannula and cannula sizing
		○ Routine use of LV unloading
		○ Timing of weaning and weaning strategies
		○ Timing of transition to semi-durable forms of MCS
		○ Optimal cannulation and decannulation strategy – surgical vs percutaneous
		○ Pro-inflammatory effects of VA ECMO
		○ Equitable delivery of VA ECMO beyond urban areas
		
		Numerous strategies remain in terms of efficacy:
		○ Currently there is no RCT evidence to support the routine use of VA ECMO in any aetiology of cardiogenic shock
		○ Recent trials and an individual patient data meta-analysis have demonstrated no benefit in the routine use in AMI-cardiogenic shock although observational data suggest that restrictive criteria adhering to the DanGer inclusion criteria may derive benefit
		○ It is clear from both observational data and clinical anecdote that certain cohorts of patients would almost certainly die without this technology and there exists limited equipoise to undertake (and small numbers to execute) randomised trials in these populations notably:
		  ○ Myocarditis
		  ○ Post transplant graft-failure
		  ○ Hypothermia
		  ○ Peri-partum cardiomyopathy
		  ○ Massive pulmonary embolism
		○ There also remains considerable uncertainty around the optimal timing of initiation of VA ECMO, age cut offs, impact of comorbid disease

		I would personally view extracorporeal CPR as a separate entity. There are compelling randomised and observational data to support efficacy, however, the challenge of this is equitable delivery outside of urban environments with rapid access to first responders and hospitals with ECPR capability. There is an ongoing Pan London initiative to address these challenges, and I am part of the steering committee for it.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The association between volume: outcome relationships and the minimum number of cases per annum needed to safely and effectively deliver this technology remains undefined. Clearly this needs to be balanced with equity of access nationally. However, there is a precedent in VV ECMO and it has been shown that 20-25 cases per year enough to maintain good outcome and safely deliver the service.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Despite a strong evidence base, it is clear from observational studies and clinical practice that cohort of patients (outlined above) would die without this technology and that more than acceptable survival rates can be achieved when VA ECMO is used in carefully selected patients before the onset of multi-organ failure. Accordingly, even in the absence of clear evidence or national guidance, it will be continued to be used and international societal guidance from the ESC, AHA and ACC supports this position. There should be a hub and spoke model for this technology to be used as described in the shock to survival document. These should be established national VA ECMO centres like VV ECMO.
18	Are people who are pregnant or have recently been pregnant eligible for VA ECMO for acute heart failure?	Yes

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent	n/a

	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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	ECMO-RRT: AMI-CS & HF-CS, VA-ECMO plus RRT vs VA-ECMO only HEMO-ECMO: AMI-CS & HF-CS, VA-ECMO + haemoperfusion vs VA-ECMO ANCHOR: AMI-CS, VA-ECMO + IABP vs Best medical Rx UNLOAD-ECMO: AMI-CS, VA ECMO + Impella CP vs VA-ECMO
21	Please list any other data (published and/or unpublished) that you would like to share.	1. Zeymer U, Freund A, Hochadel M, et al. Venoarterial extracorporeal membrane oxygenation in patients with infarct-related cardiogenic shock: an individual patient data meta-analysis of randomised trials. *Lancet* 2023; **402:** 1338–46. 2. Thiele H, Zeymer U, Akin I, et al. Extracorporeal life support in infarct-related cardiogenic shock. *N Engl J Med* 2023; **389:** 1286–97. 3. Møller JE, Engstrøm T, Jensen LO, et al. Microaxial flow pump or standard care in infarct-related cardiogenic shock. *N Engl J Med* 2024; **390:** 1382–93. 4. Lackermair K, Brunner S, Orban M, et al. Outcome of patients treated with extracorporeal life support in cardiogenic shock complicating acute myocardial infarction: 1-year result from the ECLS-Shock study. *Clin Res Cardiol* 2021; **110:** 1412–20. 5. Brunner S, Guenther SPW, Lackermair K, et al. Extracorporeal life support in cardiogenic shock complicating acute myocardial infarction. *J Am Coll Cardiol* 2019; **73:** 2355–57. 6. Ostadal P, Rokyta R, Karasek J, et al. Extracorporeal membrane oxygenation in the therapy of cardiogenic shock: results of the ECMO-CS randomized clinical trial. *Circulation* 2023; **147:** 454–64. 7. Banning Amerjeet S, Sabate M, Orban M, et al. Venoarterial extracorporeal membrane oxygenation or standard care in patients with cardiogenic shock complicating acute

		myocardial infarction: the multicentre, randomised EURO SHOCK trial. *EuroIntervention* 2023; **19:** 482–92 8. Zeymer U, Freund A, Hochadel M, et al Do DanGer-SHOCK-like patients benefit from VA-ECMO treatment in infarct-related cardiogenic shock? results of an individual patient data meta-analysis Eur Heart J Acute Cardiovasc Care 2024 Sep 25;13(9):658-661. 9. McDonagh TA, Metra M, Adamo M, et al. 2021 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure. *Eur Heart J* 2021; **42:** 3599–726.

Other considerations

22	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)?	Patients eligible for VA ECMO per annum will be around 300. The number of cardiogenic shock patients will be higher.
23	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post	Beneficial outcome measures: **DOI: 10.1161/CIRCULATIONAHA.123.064527** Adverse outcome measures: **DOI: 10.1161/CIRCULATIONAHA.123.064527**

	procedure timescales over which these should be measured:	

Further comments

24	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Undoubtedly further research is required to define optimal patient selection, timing and management of patients supported with VA ECMO. However, these trails are challenging to recruit to, costly and challenged by variable equipoise amongst practising clinicians which will inevitably result in cross-over in any standard of care arm (see published trials above).

Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Choose an item.	None		
Choose an item.			
Choose an item.			

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

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

Print name:	**Click here to enter text. Dr Sachin Shah**
Dated:	**Click here to enter text. 11/12/2024**

View results

Respondent

63 Anonymous

42:24
Time to complete

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

IP1071/2

Your information

2. Name: *

Steven Shaw

3. Job title: *

Cardiologist

4. Organisation: *

Manchester University NHS Foundation Trust

5. Email address: *

[redacted]

6. Professional organisation or society membership/affiliation: *

General Medical Council

7. Nominated/ratified by (if applicable):

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

4634423

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, as communicated by the coordinator/administrator.

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 have 13 years of experience in selecting patients for ECMO and managing patients on ECMO.

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.

Our team at Wythenshawe has been using VA ECMO since 2007/8. I am also aware of its use and the clinical outcomes within the all the heart transplant units of the UK, where it is currently commissioned as bridge to transplant decision.
Similar technology is used by respiratory intensive care units to provide Veno-Veno (VV) ECMO, it is just they cannulate vein to vein, rather than vein to artery.

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

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

14. Does the title adequately reflect the procedure?

- (●) Yes
- ( ) Other

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

Yes

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

The technology has been around for a long time (we have been using it for 17 years). However, the use of VA ECMO has generally been confined to transplant centres of the UK, and I presume there is a consideration of wider use.

17. 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.

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

in addition to standard care.

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

no

20. Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?

no

21. Do you think the guidance needs updating?

only if guidance extends to outside of transplant centres.

Current management

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

For cardiogenic shock, intravenous inotropes and intra-aortic balloon pumps are the usual standards of care.

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?

The Impella devices are another technology that are gaining popularity around the world in the management of cardiogenic shock. These devices can be used as an alternative, or even in combination with VA ECMO for selected patients.

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?

to stabilise them from cardiogenic shock, allowing a decision to be made whether we can bridge them to a heart transplant, a long term VAD, or to recovery in the setting of an acute reversible cause.

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

typically young patients with minimal co-morbidity and a chance of transplant or long term VAD as an exit strategy if their hearts are irreversibly damaged.

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

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

    It could lead to more lives saved of young people with cardiogenic shock.

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

    You need an MDT consisting of experienced cardiologists, cardiothoracic surgeons, cardiac intensivists, nurse specialists in mechanical support, access to acute theatres, intensive care unit capacity. Each patient on VA ECMO is very labour intensive both before, during and after the intervention. Often multiple trips to theatre are necessary.

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

    Yes, it would be imperative that specific training is required before using it, not for the implantation of ECMO, but for the selection of patients and the management of patients once on VA ECMO.

Safety and efficacy of the procedure/technology

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

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

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

    Stroke, massive haemorrhage, infection, haemolysis, ARDS, equipment failure are well known complications.
    Anecdotal adverse events include having a patient stabilise on VA-ECMO but has no options to "exit" from VA ECMO.

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

    Survival at 90 days

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

    I always have concerns about what comes next after VA ECMO, because it offers only very short term circulatory support. You always need to be forward thinking. Most patients in my experience have such poor hearts that they need a heart transplant or long term VAD to survive. This means they need to go on and have further (often multiple) operations, and we always feel its important that a transplant surgeon is involved, so that cannulation of then VA ECMO and subsequent management of the patient doesn't jeopardise the chance of being a candidate for transplant etc.

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

    not really. Used worldwide in dedicated centres.

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

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

Abstracts and ongoing studies

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

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

I would invite you to look at the Mechanical Cirulatory Support Annual Report that is published on the NHSBT website each year. This documents the current commissioned use of VA ECMO (contained within the section "Adult Short Term Devices used for Bridging") to gain an idea of current numbers at each of the 6 existing centres, the patient characteristics and survival statistics.
https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/31999/nhsbt-mechanical-circulatory-support-report-2223.pdf

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

as described above - all commissioned uses of VA ECMO at the 6 transplant centres are subject to a national registry.
There are also international registries, the largest i know being the ELSO registry:
https://www.elso.org/registry/internationalsummaryandreports/internationalsummary.aspx

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)?

I am unsure

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

    Beneficial outcome measures.

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

Survival at 30days, 90 days and 1 year are the key measurements we make in current UK practice.

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

Adverse outcome measures.

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

Stroke, Death, Major Haemorrhage, are the main ones

Further comments

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

n/a

Declarations of interests

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

41. Type of interest: *

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

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

none

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

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

- (●) I agree
- ( ) I disagree

Signature

44. Name: *

Steven Shaw

45. Date: *

01/10/2024

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

Name:	Andrew Ludman
Job title:	Chair, Guidelines & Practice Committee; Consultant Cardiologist
Organisation:	British Cardiovascular Society; Royal Devon University Healthcare NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	British Cardiovascular Society
Nominated/ratified by (if applicable):	British Cardiovascular Society
Registration number (e.g. GMC, NMC, HCPC)	GMC

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.

The BCS has consulted its members who have expertise with VA ECMO, and we present a synthesis of their comments.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own? – If your specialty is involved in patient selection or referral to another specialty for this	The BCS approached a group of members who have direct experience using the technology. One contributor (Alastair Proudfoot) is a consultant intensivist and lead for cardiogenic shock at Barts Heart Centre, London. His service receives around 100 referrals for VA ECMO annually, and around 50 patients are ultimately placed on the technology. He is an internationally recognised expert in cardiogenic shock. Another contributor (Ross Thomson) is a specialist registrar in cardiology working in advanced heart failure, transplantation and mechanical circulatory support at Harefield Hospital. The technology is used by cardiologists and intensivists working in cardiothoracic centres, with input from multiple other specialties (discussed below). Referrals for consideration of this technology come from a wide variety of sources, including intensive care units, cardiology departments and emergency departments across secondary and tertiary care.

	procedure/technology, please indicate your experience with it.	
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	No. Acute heart failure (AHF) is a clinical syndrome with a broad spectrum of severity. The majority of patients with AHF will have less severe signs and symptoms and can be successfully managed using conventional (medical) therapies. Only a minority of patients will go own to develop cardiogenic shock, a life-threatening syndrome characterised end-organ hypoperfusion. Of the patients with cardiogenic shock, only a minority will require VA ECMO. The title should reflect the use of the technology specifically in patients with cardiogenic shock. The technology has been in use for over 30 years. It is already a component of the standard of care for patients with cardiogenic shock refractory to medical therapy, in the small number of centres with access to the technology. While there have been minor advancements in the design and function of specific circuit components, the technology has not fundamentally changed over the past 10 years.
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?	The technology will serve as an adjunct to standard care for patients with cardiogenic shock. It will only be required in the subset of patients who fail to respond adequately to standard (medical) therapy.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure?	There have been no significant changes to the technology, but the evidence base has expanded substantially.

	Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	

Current management

6	Please describe the current standard of care that is used in the NHS.	The current standard of care for patients with cardiogenic shock includes management of volume status, inotropes and vasopressors to augment cardiac output and maintain systemic vascular resistance and supportive therapy for end-organ dysfunction (e.g. renal replacement therapy for acute kidney injury or ventilation for respiratory failure due to pulmonary oedema). Mechanical circulatory support (e.g. VA ECMO, Impella) is available in a small number of specialised centres (6 AHF centres, 8 nationally commissioned severe acute respiratory failure centres (with some overlap with the AHF centres), a few other cardiothoracic centres) and would be considered standard of care for patients in these centres, but its availability is limited.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	VA ECMO pumps oxygenated blood from the venous to the arterial vasculature, increasing systemic perfusion and supporting or replacing the role of the heart (and lungs) in the circulation. Several technologies have similar mechanisms of action: A temporary surgical ventricular assist device is implanted by a cardiac surgeon through a median sternotomy (or, less commonly, a thoracotomy). It can be configured for right, left or biventricular support. For left heart support, a drainage cannula is placed in the left ventricle (or, less commonly, left atrium) and an outflow cannula in the aorta. For right heart support, a drainage cannula is placed in the right atrium and an outflow cannula in the pulmonary artery. The drainage and outflow cannula(e) is/are connected to an extracorporeal pump, which moves blood from the venous to the arterial circulation. An oxygenator can be added to the right ventricular circuit, if necessary. The CentriMag magnetically levitated centrifugal flow pump (Abbott) is the most commonly used system in the UK. The components used in a temporary surgical ventricular assist device are very similar (or even identical) to those used in a VA ECMO circuit, but the configuration is different. Compared to implant of VA ECMO, which can often be performed in an awake patient under local anaesthetic, implant of a temporary surgical ventricular assist device is a much invasive procedure, requiring general anaesthetic. A temporary surgical ventricular assist device, however, permits much easier

		patient mobilisation, is associated with a lower risk of circuit and access site complications, and directly ‘unloads’ the left ventricle. The Impella microaxial flow pump (Abiomed, Johnson & Johnson MedTech) is a transcatheter device that is inserted via the femoeral or subclavian artery and sits across the aortic valve, with an inlet in the left ventricle (LV) and an output in the aorta. It pumps blood from the LV to the aorta, improving systemic perfusion. Unlike VA ECMO, it cannot oxygenate the blood, only supports the LV, and achieves a lower blood flow rate. A recent randomised trial (doi: 10.1056/NEJMoa2312572) showed that Impella improved outcomes in a carefully selected group of patients with cardiogenic shock secondary to acute myocardial infarction.

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 technology restores blood flow and thereby end-organ perfusion, treating the immediately life-threatening consequences of cardiogenic shock. It thereby acts as a 'bridge' either to recovery of native heart function or heart replacement therapy (transplantation of durable left ventricular assist device).
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with severe cardiogenic shock, refractory to medical therapy, who have a realistic probability of native heart recovery (e.g. myocarditis, drug toxicity, hypothermia, acute myocardial infarction with left ventricular dysfunction post-revascularisation, primary graft dysfunction post-heart transplantation), or who are candidates for heart replacement therapy. Patients with cardiac arrest refractory to standard management who have a high probability of good neurological outcome.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	There are currently no defined pathways of care for cardiogenic shock and no national level audit data to understand treatment use, patient outcomes and costs to the NHS. This almost certainly results in heterogenous care and outcomes nationally as well and inequity of access. A similar situation applies to VA ECMO, specifically. As outlined in the Shock to Survival framework document, it is conceivable that organisation of regionalised pathways for cardiogenic shock would improve equity of access to optimal and best care, including the use of VA ECMO, and thereby patient outcomes.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	A national agenda (supported by relevant societies BCIS, BCS and ICS) to improve and embed the early recognition and escalation of patients with cardiogenic shock including greater equity of access to diagnostic tests, specifically point of care cardiac ultrasound. Formation of regional cardiogenic shock networks with clear, 24/7, referral pathways to regional shock centres with the capability to support patients with all severities of cardiogenic shock including those requiring VA ECMO. In addition, shock centres would provide the capability to retrieve those patients on VA ECMO who cannot be moved via conventional methods. See: https://ics.ac.uk/resource/shock-to-survival-report.html Equitable access to experts in cardiogenic shock and the use of mechanical circulatory support technologies through a regionalised, single point of contact MDT as outlined above. An agreed set of standards and national service specification for (shock) centres that care for patients with both cardiogenic shock and VA ECMO.

		Capability for both univentricular and biventricular short- term MCS devices as a bridge to decision, bridge to advanced heart failure treatment and as a bridge to long-term MCS to assess transplant candidacy Shock centres which work closely with supra-regional AHFCs, where not co-located, to ensure all patients with CS who might benefit from a heart transplant are discussed Support education and training in the awareness, recognition and management of cardiogenic shock from shock centres across their geographical network with and embedding of locally approved escalation protocols across the network A network governance structure to support audit, quality improvement and bi-directional learning across the network A nationally agreed core outcomes data set embedded into national audit.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Safe and effective delivery of the technology requires a highly skilled multidisciplinary team. Much of this can be extrapolated from existing service specification for VV ECMO. The technology – and cardiogenic shock itself – are associated with multisystem complication, and access to wider specialist services including, but not limited to, vascular surgery, interventional radiology, neurology and obstetrics is required. In patients who do survive, their stay in critical care can be prolonged and allied health specialty input is crucial to recovery. Many patients will not survive, despite optimal care, and specialist palliative care input is required to support patients and their families. Psychological and psychiatric services are often required.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience)	Some harms are associated with the underlying condition (cardiogenic shock) and some with the technology itself Stroke: Ischaemic 3.9%, haemorrhagic 2.9% Bleeding: 30% Limb ischaemia: 10% Infection: 16% Haemolysis:

	Theoretical adverse events	Liver Injury: 27% Acute Kidney injury: 50% with need for renal replacement in 20% Mesenteric Ischaemia: 9%

14	Please list the key efficacy outcomes for this procedure/technology?	**See: DOI: 10.1161/CIRCULATIONAHA.123.064527**
		Mortality: In-hospital, 30d, 180d and 1 year survival
		ICU & Hospital length of stay
		Organ support days (respiratory, cardiac and renal)
		Cause of death: Cardiovascular, non-cardiovascular, undetermined
		Safety events:
		• CNS Injury: All stroke, Symptomatic hypoxic-ischemic injury, Covert CNS infarction or haemorrhage, Neurologic dysfunction (acutely symptomatic) without CNS injury
		• Bleeding events: VARC 1-5
		• Vascular and Structural cardiac complication
		  ○ Major
		  ○ Minor
		• Access related non-vascular complications
		  ○ Major
		  ○ Minor
		• Bleeding VARC classification 1-5
		• Organ System Dysfunction
		  ○ Hepatic dysfunction/Liver Injury
		  ○ Acute Kidney Injury
		  ○ Mesenteric Ischemia
		  ○ Pulmonary Haemorrhage
		  ○ Refractory Pulmonary oedema
		• Haematological events
		  ○ Haemolysis
		  ○ Thrombocytopenia
		  ○ Infection
		  ○ Percutaneous insertion site infection
		  ○ Blood stream infection
		  ○ Sepsis Device Malfunction

		• General Device Malfunction
		  ○ Device Thrombus
		  ○ Accidental Decannulation/Device Cannula Migration
		• Vascular & cardiac structural complications
		  ○ Major
		  ○ Minor
		
		HRQoL: Euro-QOL-5D-5L, Lawton Instrumental Activities of Daily Living, modified Rankin scale
		
		Hospital-free days
		
		Hospitalizations: all cause, cardiovascular, heart failure related, non-cardiovascular, undetermined
		
		Cost: QALY

15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Numerous uncertainties remain in terms of management: • Optimal management strategies on VA ECMO: target oxygenation, target anticoagulation, optimal blood flow, target MAP, use of inopressors, monitoring, minimisation of complications including routine use of a distal leg perfusion cannula and cannula sizing • Routine use of LV unloading • Timing of weaning and weaning strategies • Timing of transition to semi-durable forms of MCS • Optimal cannulation and decannulation strategy – surgical vs percutaneous • Pro-inflammatory effects of VA ECMO • Equitable delivery of VA ECMO beyond urban areas Numerous uncertainties remain in terms of efficacy: There is no randomised trial evidence to support the routine use of VA ECMO in any aetiology of cardiogenic shock Recent trials, and an individual patient data meta-analysis, have demonstrated no benefit in the routine use in AMI-cardiogenic shock ,although observational data suggest that a subset of patients meeting the inclusion criteria DanGer Shock trial may derive benefit

		It is clear from both observational data and clinical anecdote that certain cohorts of patients would almost certainly die without this technology and there exists limited equipoise to undertake (and small numbers to execute) randomised trials in these populations notably: • Myocarditis • Post transplant graft-failure • Hypothermia • Peri-partum cardiomyopathy • Massive pulmonary embolism There also remains considerable uncertainty around the optimal timing of initiation of VA ECMO, age cut offs, impact of comorbid disease
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	See above In addition, the association between volume: outcome relationships and the minimum number of cases per annum needed to safely and effectively deliver this technology remains undefined. Clearly this needs to be balanced with equity of access nationally.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Despite the lack of a strong evidence base, observational studies and clinical practice demonstrate that there exists a cohort of patients (examples provided above) that would die without this technology. Good survival rates can be achieved when VA ECMO is used in carefully selected patients before the onset of multi-organ failure. Accordingly, even in the absence of clear evidence or national guidance, the technology is likely to still continue to be used. International societal guidance from the European Society of Cardiology, American Heart Association and American College of Cardiology supports this position.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are	n/a

	only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	
19	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	ECMO-RRT: AMI-CS & HF-CS, VA-ECMO plus RRT vs VA-ECMO only HEMO-ECMO: AMI-CS & HF-CS, VA-ECMO + haemoperfusion vs VA-ECMO ANCHOR: AMI-CS, VA-ECMO + IABP vs Best medical Rx UNLOAD-ECMO: AMI-CS, VA ECMO + Impella CP vs VA-ECMO HERACLES: VA ECMO + Impella CP vs VA ECMO + IABP
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)?	Around 600 patients per year, across the UK
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement	Beneficial outcome measures: See above and the SHARC consensus statement (doi: 10.1161/CIRCULATIONAHA.123.064527) Adverse outcome measures: See above and the SHARC consensus statement (doi: 10.1161/CIRCULATIONAHA.123.064527)

	for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	

Further comments

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

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Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Indirect	Advisory Board, Getinge (Alastair Proudfoot)	**June 2024**	**August 2024**
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:	**Andrew Ludman** **On behalf of British Cardiovascular Society**
Dated:	**16/10/2024**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

Name:	Espeed Khoshbin
Job title:	Consultant in cardiac surgery, transplantation, and mechanical circulatory support
Organisation:	Royal Brompton and Harefield Hospital as part of Guys and St Thomas Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	The Society of Cardiothoracic Surgeons of GB & I (SCTS)
Nominated/ratified by (if applicable):	SCTS
Registration number (e.g. GMC, NMC, HCPC)	4292524

How NICE will use this information:

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

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake?	I have been involved in the use of venoarterial extracorporeal membrane oxygenation (VA ECMO) since 2002 when I worked at Glenfield Hospital (the national ECMO centre). I have experience in the use of this technology in adults as well as the paediatric and neonatal population. I have contributed to the advances in VA ECMO clinically and through research for the last 22 years. I am a cardiac surgeon with a specialist interest in heart and lung transplantation and mechanical circulatory support. In my current practice I use VA ECMO very regularly as a bridge to recovery (post cardiotomy, acute rejection and viral myocarditis), bridge to heart transplantation in a decompensated heart failure patient, bridge to bridge (to other mechanical circulatory support systems such as BIVAD or total artificial heart) to increase the duration of cardiac support and post transplantation for primary allograft dysfunction (PAD). I implant both central and peripheral VA ECMO. In my experience working for the NHS, VA ECMO is being increasingly and more widely used as a viable option to support cardiac, respiratory and multi organ dysfunction. It is increasingly used for post cardiotomy, pre and post heart and lung transplantation and as ECMO for cardiopulmonary resuscitation (ECPR). I receive an increasing number of referrals from other trusts and cities for the use of this technology and our trust provides means for mobile ECMO. This would enable safe transfer of patients from other hospital to our ECMO centre.

	− 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, my abdominal counterparts use a similar technology to improve the yield during abdominal organ procurement. This is called abdominal normothermic regional perfusion (A-NRP). We are a referral centre for VA ECMO and have an active ECPR and mobile ECMO program. We frequently receive shock calls and accept patients for transfer to my unit for VA ECMO as a bridge to recovery or transplantation.
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	My doctoral research degree MD published in the British Library in 2008: ECMO for systemic inflammatory response syndrome (SIRS) and multi organ dysfunctional syndrome (MODS). I have conducted several clinical ECMO research projects involving patients as part of my doctoral research and device related projects such as the efficiency of ECMO oxygenators. This resulted in a more efficient circuit, a significant reduction in the ECMO circuit size and hence the change to the current smaller circuits, made ECPR and mobile ECMO possible. It also reduced the inflammatory response to ECMO and MODS. I have developed and published an animal and laboratory model of SIRS and MODS for use in ECMO related research. I have several publications in this topic and written a book chapter on post cardiotomy VA ECMO. I am an expert reviewer for the national institute of health care research (NIHR) on ECMO. I am an honorary clinical senior lecturer at Imperial College London.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is	Yes It may also be referred to as “IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for management of cardiogenic shock in adults” This is an established procedure in an ECMO specialist centre. To majority of other centres however it may be novel technology.

	it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	Yes. This is in my opinion the standard of care in highly specialised centres, however in other units it is likely to be an addition to the existing standard of care that will save lives.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	The technique has evolved to allow safe insertion and accurate positioning of the VA ECMO percutaneously using transthoracic or trans oesophageal echocardiogram; hence it is used more often as a bail out strategy in acutely decompensating heart failure patients. If the ECMO is placed after cardiac arrest, it is named ECMO CPR (E-CPR). The procedure is further modified to maintain distal limb perfusion by insertion of a distal perfusion cannula using ultrasound or fluoroscopy where a cannula in inserted into the femoral artery in opposite direction to keep the limb perfused with blood from the circuit. Yes for the reasons mentioned in the above sentence. There are well established VA ECMO and E CPR protocols and standards of practices (SOPs). This has made the process safer and more efficient.

Current management

6	Please describe the current standard of care that is used in the NHS.	Currently in many centres the standard of care for patients with cardiogenic shock is either the use of inhaled nitric oxide for right ventricular support or systemic inotropic support alone. If the patient does not respond and is too sick to be transferred to an ECMO centre or has other co morbidities that prohibits the use of VA ECMO, the patient is then palliated.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Another standard of care that is commonly used is the use of intra-aortic balloon pump (IABP) mechanical support / technology. This is a percutaneous device that is still used as a possible solution in many centres to augment mean arterial pressure and coronary perfusion to improve cardiac function. The outcome of this therapy in SHOCK trial was disappointing. Another percutaneous technology is the Impella CP for left ventricular support and Impella RP for right ventricular support however they do not have the advantage of an oxygenator in the circuit for lung support. They also cannot provide full support as they augment flow across the aortic or pulmonary valve by only 3 litres. A more recent development is the Impella 5.5 which is placed surgically through a cut down in the axillary artery through a graft. This technology only provides left sided heart support but can reach higher flows of above 5 litres. The above devices are only licenced for short term use. This device may be used in combination with VA ECMO to provide biventricular support and is called ECPella. Other similar technologies are more invasive just like the central VA ECMO. These are uni- and biventricular support systems (BIVAD) such as BIVAD Levitronix system. Compared to VA ECMO that bypasses the lung and heart, a BIVAD bypasses each individual ventricle. An oxygenator however may be added to this device (usually on the right) to provide additional lung support.

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?	This is a lifesaving procedure and when used appropriately it will produce good results. However, the appropriate use of this device will need further standardisation.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Groups that would benefit may be categorised as: Bridge to cardiorespiratory recovery a) post cardiotomy syndrome. b) viral myocarditis as we have seen with COVID and other viruses affecting the heart and lung. c) Patients with other reversible inflammatory pathologies involving the heart d) pulmonary embolism e) myocardial infarction f) patients post-transplant with primary allograft dysfunction Bridge to decision a) dilated cardiomyopathy suitability for transplantation/durable ventricular assist device. b) In patients that time is needed to make decision for palliation or not Bridge to bridge a) patients that will need complex surgery with another form of mechanical support such as BIVAD. b) Patients that decompensate before a durable long term mechanical support is placed Bridge to transplantation in patients with dilated, hypertrophic ischaemic cardiomyopathies or adult congenital heart diseases awaiting transplantation a) patients needing a new heart transplant b) patients needing a new Lung transplant c) patients needing a new Heart-lung transplant
10	Does this procedure/technology have the potential to change the current pathway or	Yes

	clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes, early, and appropriate intervention with ECMO may preserve myocardial viability and hence improve extent of recovery. Patients who have incomplete recovery will have poor quality of life and never return to work, the number of hospital admissions due to recurrent heart failure will have an impact on the patient, their family, and the health service.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Increasing the capacity in the specialist centres that provide this level of support. Increasing education nationally in respect of shock referrals. A national network for triage and referral. Improving the mobile ECMO service and increasing capacity to bridge patients to ultimately being treated appropriately.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes, 1) Training surgeons in the technique of open central and peripheral VA ECMO. 2) Intensive care training for doctors to become ECMO specialists. 3) Training for nurses other allied professionals (ECMO specialist nurses and perfusionists). 4) Training in safe implantation of the device percutaneously and surgically. 5) Training in implantation of adjuncts to VA ECMO such as distal limb perfusion cannula and Impella CP. 6) Training in the use of ultrasound, transthoracic and transoesophageal echocardiogram. 7) Training ECMO wean and femoral artery repair and distal limb embolectomy

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature)	Infection: 1) Infection such as mediastinitis in central VA ECMO if the chest is left open. 2) Ascending infection in peripheral VA ECMO. 3) Systemic sepsis and multi organ failure. Bleeding:

	Anecdotal adverse events (known from experience) Theoretical adverse events	1) Bleeding from the cannulation sites such as the aorta and right atrium in central ECMO. 2) Bleeding from the site of peripheral ECMO, most commonly the femoral vessels. 3) Spontaneous bleeding in the brain, gastrointestinal tract, and retroperitoneum. Distal limb ischaemia: 1) Small femoral vessels and restricted blood supply to the limb. 2) Hyperaemia related and venous congestion and compartment syndrome in the leg. Air entrapment: 1) Circuit failure and haemodynamic instability 2) Stroke or other end organ ischaemia. Embolism: 1) From small clots and fibrin deposits formed in the circuit tubing. 2) From large clots forming in the circuit tip. 3) Clots forming in the left ventricle and the aortic root. 4) Embolization of clots to limb and elsewhere at the time of decannulation. 5) Oxygenator failure. Haematological: 1) Consumption coagulopathy. 2) Acquired Von Willebrand syndrome. 3) Haemolysis by the circuit and the oxygenator. Lung complication 1) Pulmonary congestion. 2) ECMO lung like adult respiratory distress syndrome (ARDS). 3) Pulmonary shunt.

		Multi-organ failure 1) Systemic inflammatory response syndrome (SIRS). 2) Multi-organ failure including kidney, liver, and pancreas. 3) Confusion and neurologic syndromes Plus, other common complications of poorly patients on the intensive care unit. Useful references: 1) Lo Coco V, Lorusso R Raffa GM, et al. Clinical complications during veno-arterial extracorporeal membrane oxigenation in post-cardiotomy and non post-cardiotomy shock: still the achille's heel. J Thorac Dis. 2018 Dec;10(12):6993–7004. doi: 10.21037/jtd.2018.11.103 2) Murakami T, Sakakura T, Jinnouchi H, et al Complications related to veno-arterial extracorporeal membrane oxygenation in patients with acute myocardial infarction: VA-ECMO complications in AMI Journal of Cardiology. Volume 79, Issue 2, February 2022, Pages 170-178 doi.org/10.1016/j.jjcc.2021.10.003
14	Please list the key efficacy outcomes for this procedure/technology?	VA ECMO has proven efficacy in acute heart failure. Its use has been correlated with a good outcome in cardiogenic shock. Patients with return of spontaneous circulation appear to benefit from VA-ECMO at rates comparable to cardiogenic shock patients who never sustained cardiac arrest.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	VA ECMO in refractory cardiac arrest has limited efficacy. The role of VA ECMO alone in isolated left ventricular dysfunction is limited. ECLS-SHOCK trial (Extracorporeal Life Support in Cardiogenic Shock) and ECMO-CS trial (Extracorporeal Membrane Oxygenation in the Therapy of Cardiogenic Shock) discourage the routine use of VA-ECMO in patients with infarct-related cardiogenic shock. There is a lack of sufficient evidence regarding the benefits and safety of VA ECMO from adequately powered randomized controlled trials.

16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The use of post cardiotomy VA ECMO remains controversial due to the poor recorded outcomes.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Fewer than 10 specialist centres in the UK.
18	Are people who are pregnant or have recently been pregnant eligible for VA ECMO for acute heart failure?	Yes

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	None known to me at present
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Major trials: ECLS-SHOCK trial (Extracorporeal Life Support in Cardiogenic Shock) ECMO-CS trial (Extracorporeal Membrane Oxygenation in the Therapy of Cardiogenic Shock)

		ARREST trial (Advanced Reperfusion Strategies for Patients with Out-of-Hospital Cardiac Arrest and Refractory Ventricular Fibrillation) PRAGUE OHCA trial (Prague Out-of-Hospital Cardiac Arrest) INCEPTION trial (Early Initiation of Extracorporeal Life Support in Refractory Out-of-Hospital Cardiac Arrest) Current trials: ECLS-SHOCK trial (Extracorporeal Life Support in Cardiogenic Shock) and ECMO-CS trial (Extracorporeal Membrane Oxygenation in the Therapy of Cardiogenic Shock) ANCHOR (Assessment of ECMO in Acute Myocardial Infarction Cardiogenic Shock. NCT04184635). REVERSE (Impella CP With VA ECMO for Cardiogenic Shock, NCT03431467], UNLOAD ECMO [Left Ventricular Unloading to Improve Outcome in Cardiogenic Shock Patients on VA-ECMO, NCT05577195), PIONEER (Hemodynamic Support with ECMO and IABP in Elective Complex High-risk PCI, NCT04045873)
21	Please list any other data (published and/or unpublished) that you would like to share.	None

Other considerations

22	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)?	Unable to give an accurate estimate. I would think that in the UK this number would be less than 500 per year.
23	Please suggest potential audit criteria for this procedure/technology. If known, please describe:	Beneficial outcome measures: 1) Survival to decannulation. 2) Length of stay in intensive care. 3) Survival to discharge.

	− Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	4) 30-day survival 5) One, three- and five-year survival 6) Quality of life 7) Cost per quality-of-life years 8) Freedom from heart failure 9) Freedom from hospital admission Adverse outcome measures: 1) All-cause mortality 2) Complication (minor to major) Infection, bleeding, distal limb ischaemia, air embolism, Haematological complications, lung complications, multiorgan failure and death. 3) Need for circuit change. 4) Need for oxygenator exchange.

Further comments

24	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	There is a need for further research in the following field in my opinion: Comparing adjuncts to VA ECMO for post cardiotomy syndrome. Impella (ECPella) versus other modes of left ventricular (LV) venting. Cost-effectiveness of adjuncts such as Impella versus other modes of LV venting during VA ECMO. Trial of VA ECMO as a bridge to transplantation vs. BIVAD. VA ECMO versus other mechanical circulatory supports such as LVAD in low INTERMACS class I and II patients.

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Declarations of interests

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

☒ 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:	**Espeed Khoshbin**
Dated:	**10/11/2024**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: **IP1071 Extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults**

Your information

Name:	Dr Dale Gardiner
Job title:	Chair, FICM's Professional Affairs and Safety Committee
Organisation:	Faculty of Intensive Care Medicine
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Fellow and Board Member of the Faculty of Intensive Care Medicine
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	4170415

How NICE will use this information:

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

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? − Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? − Is this procedure/technology performed/used by clinicians in specialities other than your own? − If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	One of the areas of responsibility for the Faculty of Intensive Care Medicine's Professional Affairs and Safety Committee (FICM PAS) is with clinical effectiveness, standard setting and guideline development. In drafting this response the Chair of FICM PAS used their own intensive care experience as a senior clinician and consulted with clinical experts in the field of ECMO.

2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. I have had no involvement in research on this procedure. Other (please comment) N/A
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain.	Yes We consider that since this NICE guidance was first published in 2014 the use, availability and indications of ECMO for heart failure (cardiac ECMO) have expanded. The NICE recommendation in 2014 was that the “evidence on the efficacy of extracorporeal membrane oxygenation (ECMO) for acute heart failure in adults is adequate but there is uncertainty about which patients are likely to benefit.” Additionally that NICE “encourages further research into ECMO for acute heart failure.” While the evidence which has emerged since 2014 is mainly case reports / case series, with all their limitations, it is important to update the NICE guidance to best reflect and advise on current best practice. Globally the demand and use of cardiac ECMO is increasing. Anecdotally the UK ECMO centres are getting increasing requests for cardiac ECMO. There is emerging consensus that this activity should be more directly commissioned in the same way that respiratory ECMO is. Currently it isn't and although some transplant centres can fund it via their Transplant / Ventricular Assist Device pathways not every ECMO centre is able to do this.

		Outcomes for cardiac ECMO are still not as good as for respiratory ECMO. https://www.elso.org/registry/elsoliveregistrydashboard.aspx There are however conditions with a more favourable outcome with cardiac ECMO these include acute/fulminant myocarditis, peripartum cardiomyopathy, overdose, VT/VF storm and to a lesser extent acute pulmonary embolism. None of these were considered in detail in the 2014 Guidance. Example recent papers are: Ca channel blocker OD P3: ECMO and Calcium Channel Blocker Overdose: A Systematic... : ASAIO Journal (lww.com) Acute fulminant myocarditis Outcomes With Peripheral Venoarterial Extracorporeal Membrane Oxygenation for Suspected Acute Myocarditis: 10-Year Experience From the Extracorporeal Life Support Organization Registry | Circulation: Heart Failure (ahajournals.org) Peripartum cardiomyopathy Extracorporeal membrane oxygenation in peripartum cardiomyopathy: A review of the ELSO Registry - PubMed (nih.gov) It is essential that appropriate pathways should be in place to ensure that pregnant/recently pregnant women are able to access specialised services such as ECMO in line with current national guidance for non-pregnant patients. Specific inclusion of this indication in any updated NICE guidance will support equity in access. The 2014 NICE guidance focussed predominantly on post-cardiotomy ECMO, the most common indication any update should expand on those indications. Updated guidance from NICE will lay out the evidence base for any expansion of service. Additionally the indications for use can be better defined which will help with equity of access and in improving outcomes.

	How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	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.
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?	Cardiac ECMO (predominantly VA ECMO) is offered as part of a multimodal bundle of management delivered by highly specialised multidisciplinary shock teams in isolated centres and regions where it is considered a standard of care for patients with the most severe cardiac failure from reversible causes. It is also routinely used within these specialised centres for support of the cardiac surgical patient and for supporting patients who require heart transplantation. The lack of national commissioning has created substantial inequity of access and considerable variation in practice.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	There has been considerable growth in the expertise required to treat patients with VA ECMO in recent years with particularly focus on systems of care to identify potential candidates and refined standardise clinical procedures to deliver high quality care. ECMO machines have been substantially redesigned in recent years and are now more efficient, simpler, lighter and more user friendly.

Current management

6	Please describe the current standard of care that is used in the NHS.	As above. There is regional and local variation in what is considered standard of care in UK patients who develop cardiac arrest or cardiogenic shock and clinical outcomes have remained consistently poor for the last 30 years. 92% of patients with out of hospital cardiac arrest and 50% of those with cardiogenic shock do not survive. In centres who offer VA ECMO, or who transfer in such patients from other hospitals, this has become a standard of care for a highly selected cohort of patients with locally reported outcomes being compelling for improved mortality.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	There are variety of mechanical support devices such as microaxial flow pumps and centrally inserted BiVADs. However VA ECMO is the only therapy currently available that can be rapidly implanted to provide complete haemodynamic and respiratory support.

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?	VA ECMO is the only therapy available that can be rapidly deployed to replace the entire circulation. In patients with the most severe cardiogenic shock or refractory cardiac arrest it is the only treatment available that gives a meaningful chance of survival. Case series and registries suggest very favourable outcomes for certain conditions such as fulminant myocarditis and certain drug overdoses (as described above). There is a growing body of randomised data suggestive of a mortality benefit in refractory cardiac arrest.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	As described above. Patients who present with the most severe forms of cardiogenic shock or refractory cardiac arrest from reversible cardiac conditions who can be rapidly identified and established on ECMO quickly are most likely to benefit. This is a very small proportion of the total cardiogenic shock population. The Intensive Care Society recently published the shock to survival report which suggests refined systems of care to improve outcomes in cardiogenic shock, including access to VA ECMO. https://ics.ac.uk/static/8d541809-af1e-4e46-89c0d4382fd41bc6/Shock-to-Survival-Reportfinal.pdf There is concern from clinicians involved in maternal critical care that these patients do not have equity of access to ECMO services.It is essential that appropriate pathways should be in place to ensure that pregnant/recently pregnant women are able to access specialised services such as ECMO in line with current national guidance for non-pregnant patients. Specific inclusion of this indication in any updated NICE guidance will support equity in access.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	VA ECMO is the only treatment that can be initiated rapidly enough in the most severe forms of cardiogenic shock or cardiac arrest to meaningfully alter the patient's outcome. When utilised by experts using robust systems of care VA ECMO can reverse an unsurvivable level of catastrophic illness and provide the safety and stability for the underlying pathology to recover. An example of this is that the reported survival from the ELSO registry for patients with fulminant myocarditis treated with VA ECMO is over 70%.

11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	For VA ECMO to be effective it must be delivered by highly trained experts in robust systems of care that rapidly identify those who may benefit, safely transfer them to a site where they can be established, maintained and subsequently weaned from therapy. There are currently 13 centres in the UK offering this service but there is variation in practice and in outcomes. Updated NICE guidance will help drive forward standardisation of indications and acceptance criteria, equity of access and improved patient outcomes.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	

16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. A minority of hospitals, but at least 10 in the UK. Fewer than 10 specialist centres in the UK. Cannot predict at present.

Abstracts and ongoing studies

18	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent 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.	As given above. Some additional papers, focussed on cardiac arrest Yannopoulos D, Bartos J, Raveendran G, et al. Advanced reperfusion strategies for patients with out-of-hospital cardiac arrest and refractory ventricular fibrillation (ARREST): a phase 2, single centre, open-label, randomised controlled trial. *The Lancet*. 2020;396(10265):1807-1816. doi:10.1016/S0140-6736(20)32338-2 Belohlavek J, Yannopoulos D, Smalcova J, et al. Intraarrest transport, extracorporeal cardiopulmonary resuscitation, and early invasive management in refractory out-of-hospital cardiac arrest: an individual patient data pooled analysis of two randomised trials. Suverein MM, Delnoij TSR, Lorusso R, et al. Early Extracorporeal CPR for Refractory Out-of-Hospital Cardiac Arrest. New England Journal of Medicine. 2023;388(4):299-309. Raphalen JH, Soumagnac T, Blanot S, et al. Kidneys recovered from brain dead cardiac arrest patients resuscitated with ECPR show similar one-year graft survival compared to other donors. Resuscitation. 2023;190:109883.

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

Other considerations

21	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	
22	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: Adverse outcome measures:

Further comments

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

NICE National Institute for Health and Care Excellence

Declarations of interests

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

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

☒ 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:	**Dale Gardiner**
Dated:	**20/05/2024**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

Name:	Alex Rosenberg
Job title:	Consultant Intensivist
Organisation:	Harefield Hospital, Part Of Guys and St Thomas's NHS Foundation Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	FFICM
Nominated/ratified by (if applicable):	n/a
Registration number (e.g. GMC, NMC, HCPC)	6114809

How NICE will use this information:

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

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own?	I use this therapy on a daily basis in my clinical practice. I am a consultant intensivist specialising in cardiothoracic critical care, extra corporeal life support and heart and lung transplantation. I am the clinical lead for the ECMO service in Harefield hospital which is the UK's largest VA ECMO service. I am a consultant in the ECMO retrieval service where we establish ECMO in patients suffering from severe cardiac and respiratory failure remotely then transfer them to our hospitals. I have recently been seconded to 2 other London hospitals to support them in setting up new VA ECMO programs so have experience in leading a large service and setting up new ones de novo. I co-direct the mechanical life support program, a group delivering high quality education in ecmo and mechanical circulatory support nationally and internationally. I am a member of the NHS London cardiogenic shock board where I chair the education and training sub committee. I am the director of the UK eCPR summit which has now run 2 national conferences on ecmo in cardiac arrest and am a member of the eCPR committee of EUROELSO. The work that I have lead has been recognised with the ELSO gold centre of excellence award for Harefield Hospital, and the Quality improvement initiative of the year and patient safety, education and training awards at the HSJ patient safety awards in 2023. I recently undertook a piece of work trying to answer this exact question so can provide accurate data. We have not yet published this work however I have identified with a high degree of accuracy that between 2012 and 2022 a total of 2117 patients were treated with VA ECMO in the UK for acute cardiac failure. Of these 2117 patients 302 were for patients in cardiac arrest at the

	– If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	time of cannulation. I have more granular data on these patients that I'd be happy to share with NICE as part of this work if requested? This should also soon be published and available in the literature. Currently VA ECMO is only delivered in a small number (13) of specialist centres who are mostly commissioned for either VV ECMO for SARF or heart and lung transplantation. There is increasing interest in setting up ECMO services by other centres who have identified that they have patients who will potentially benefit (usually presenting to heart attack centres in cardiogenic shock or cardiac arrest). There is also currently a lot of interest from pre hospital HEMS service to deliver pre hospital ECMO for out of hospital cardiac arrest. VA ECMO is a resuscitative tool and so can be used in a wide range of patients – any disease which can cause cardiogenic shock or cardiac arrest. Specialists in VA ECMO can come from a wide range of backgrounds including intensive care, cardiology, cardiac surgery, emergency medicine and others. The therapy is delivered best by multidisciplinary teams working together. As well as medical specialities nurses and perfusionists are fundamental to a service. As part of the ongoing quality improvement of our own ECMO service our team have done in depth data analysis around patient selection and systems and processes for rapid identification, risk stratification, candidacy assessment, cannulation, stabilisation and ongoing care. I would be happy to share or present this work to NICE if it would be helpful.
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. Other (please comment)
3	Does the title adequately reflect the procedure?	Probably! There is some nuance in modern practice though that this title doesn't capture. We tend to talk about "Short term mechanical circulatory support" (StMCS) when describing this therapy.

	Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	VA ECMO is one type of StMCS but there are others. More recently we have learned that to manage patients with very severe cardiogenic shock or cardiac arrest the best approach is to choose the best circulatory support device rather than be restricted to a single device (like VA ECMO). There are several clinical situations when patients need to be treated with more than one device. The term “acute heart failure” is ok. We are talking about patients with very severe cardiogenic shock or who are in cardiac arrest. Realise it might make the title too verbose but could these two states be spelled out? “Short Term Mechanical Circulatory Support for adults in cardiogenic shock or cardiac arrest” The procedure is neither innovative nor novel it has been routine clinical practice since the 1970s. Comprehensive data sets have been submitted to the international ELSO registry of 61,540 patients treated with VA ECMO for cardiogenic shock and a further 19,204 patients treated with VA ECMO for cardiac arrest. Over the last 10 years the understanding of how to use this device and which patients benefit has improved considerably and high performing centres have set up regional systems of care which show improved outcomes for their populations. Established practice and no longer new.
4	Does this procedure/technology have the potential to replace current standard care or would it be used as an addition to existing standard care?	VA ECMO is standard care in some areas of the UK but is unavailable in others. This inequity of access is the current major inadequacy in the delivery of this therapy.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	Devices have become smaller and simpler. A modern ECMO device is a simplified circuit with monitoring built into it. This is simply clicked into a console and then the circuit connected to the cannulae in the patient. This makes training large numbers of less specialised team members straightforward for the day to day management and safety procedures. Devices weigh around 10kg to make transfer easier. Over the last 5 years more functionality has been built into machines to enable fine tuning and individualisation of therapy. The evidence has changed but the interpretation is nuanced and probably not entirely clear to those not involved in delivering this therapy on a daily basis. Since the last NICE guidance there have been 6 RCTs published comparing VA ECMO to conventional therapy. 3 of these are in cardiogenic shock from acute coronary syndrome, 3 of them are in cardiac arrest. The 3 RCTs in cardiogenic shock patients are EUROSHOCK, ECLS SHOCK and ECMO CS. All three of these trials looked at a population of patients with cardiogenic shock caused by acute coronary syndrome (ACS-CS). In our clinical practice we know that this is a high risk population for VA ECMO and that they are often better managed with a different type of StMCS (see

		DANGERSHOCK trial). EUROSHOCK failed to recruit due to COVID and was terminated after only 35 patients had been enrolled. ECLS SHOCK randomised 420 patients with 47.8% mortality in the ECMO group and 49% in the control (p=0.81). However there was a 12.5% cross over, 50% of the patients were in SCAI C shock – this is not severe enough to require VA ECMO. 15.4% of the control group were treated with a different type of StMCS that is proved to work better in ACS (Impella), no patients in the ECMO group received this treatment. 77.7% of the total population had had cardiac arrest pre cardiogenic shock, this confers very poor outcomes and in fact 24.8% of the total population died of hypoxic brain injury. Unfortunately these issues make this trial uninterpretable, the authors conclude that indiscriminate use of VA ECMO in ACS Shock does not improve mortality which is fair. There was more bleeding in the ECMO group (23.4% vs 9.6%) and more peripheral vascular complications (11% vs 3.8%). This is unsurprising and fits with clinical experience and is why only patients with the most severe forms of shock should be considered for ECMO. These increased risks are unacceptable for less severe disease. ECMO CS enrolled 117 patients with ACS-CS but looked at composite outcome that included death and cross over to requiring ECMO. They recruited a sicker cohort (SCAI D and E) which is more appropriate but the results are difficult to interpret. Primary composite outcome was 63.8% in the ECMO group and 71.2% in the control (p =0.21). Mortality was 50% in ECMO and 47.5% in control (p=ns). This trial had a 39% cross over. Interpretation is extremely challenging but proabably confirms that indiscriminate use of ECMO in ACS-CS does not improve outcomes. SAEs were the same in both groups (60.3 vs 61%) but this is impossible to interpret given the 39% cross over. There have been 3 trials published in the use of VA ECMO in cardiac arrest (eCPR). ARREST was a Baysian, single centre RCT that completed recruitment due to having met the posterior probability of 98.6% after the first recruitment block of 30 patients. This trial recruited patients in refractory cardiac arrest and randomised them to either VA ECMO or conventional advanced life support. 43% of the ECMO group survived to hospital discharge and 6% of the control group (ARR 36%, NNT 3, post prob superiorty 0.9861). Prague OHCA was a single centre RCT that randomised 256 patients to eCPR or standard ALS. They showed a 31.5% survival in the eCPR group and a 22% survival in the control group, this was not significant (p=0.09). The interpretation of this trial requires caution – 40 patients received less than 30mins CPR (14 in the ecmo group and 26 in the control) as you would expect there was no significant difference in survival in with short durations of CPR (11/14 ecpr survived, 16/26 control survived). The benefit became more obvious with genuine refractory cardiac arrest, in those that had >45 CPR 20/91 survived in the ECMO group and 6/73 survived in the control

		group. Further more of the 6 survivors in the control group 4 were cross overs and were treated with ECMO. If this trial is reanalysed as a per protocol analysis the survival benefit becomes significant. Finally the survival of 22% in the control group was surprisingly high for this cohort of cardiac arrest patinets. When these 2 trial are put together as a metaanalysis (286 patients) there is a significant mortality benefit for the ECMO group (HR0.44 p=0.0001) and this becomes larger if only patients who present in VT or VF are included. INCEPTION was the first multicentre RCT to look at eCPR vs conventional CPR it recruited 160 patients with 20% survival with favorable neurological outcome in the ECMO group and 16% in the conventional group (p=0.52). This trial needs to be interpreted cautiously however. The first 2 trials were conducted by experts in delivering eCPR whereas INCEPTION was more pragmatically rolled out. This meant there was significant variability in the delivery of the protocol and it took much longer to get the patients on ECMO (median 74 mins compared to 58mins in ARREST). The interpretation of this is probably that this intervention is challenging and complex and will not confer benefit if rolled out in a rapid “pragmatic” fashion, it needs to be performed by experts operating in well developed systems. On top of these 6 RCTs there have been a great many non-randomised trials conducted and published and our understanding of this therapy is greatly improved since the last NICE guidance was issued.

Current management

6	Please describe the current standard of care that is used in the NHS.	There is a high degree of variation in practice within the NHS for patient with cardiogenic shock and cardiac arrest. In several areas patients will be treated with VA ECMO and other forms of STMCS by well developed systems that identify, stabilise and escalate patients who are appropriate for advanced therapies. In others these therapies are completely unavailable and patients are treated with pharmacological therapies in non specialist intensive care units. Mortality is extremely high for this cohort.

7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	There are other STMCS devices available and in use in the NHS. These include Intra Aortic Balloon pump (IABP) and Impella. The data on IABP is far from compelling and the device is only capable of providing a very small amount of mechanical circulatory support, usually far less that the patient needs. Impella is a highly effective therapy, particularly in the context of ACS but is not a competitor to VA ECMO and is actually extremely complimentary. Modern cardiogenic shock services should be able to offer both of these treatments and often patient swill receive both devices concurrently. Surgically implanted devices such as LVADs aren't possible to use in the context of cardiogenic shock or cardiac arrests due to the time frames required to implant the device and the invasiveness of the procedure in unstable patients. These devices are sometimes required as escalation therapy one the patient has been stabilised with STMCS but this tends to be days or weeks later. Sometimes patients can be stabilised with inotropic medication, however in the most severe forms of cardiogenic shock this tends to be unsuccessful and mortality for SCAI E shock is >75% with this strategy. Conventional ALS for cardiac arrest confers poor outcomes with morality around 100% after 53% of CPR. VA ECMO is currently the only therapy which can be deployed in the time frame required for shocked and arrested patients that provides total circulatory and respiratory support.

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?	When used correctly this device is life saving. I am happy to provide our local data but as a headline in the last year in my hospital 71% of patients put on VA ECMO for cardiogenic shock and 50% for cardiac arrest have survived to discharge home. The shock patients are SCAI E so have at least a 75% mortality according to international data. The cardiac arrest patients are in refractory arrest and so have approaching a 100% mortality. Our service also provides opportunities for patients having procedures in hospital by resucing them from complications or providing intraprocedural support. We have supported patients post cardiac surgery, rescued patients undergoing TAVI who have suffered cardiac arrest and have provided intraprocedural support during VT ablation.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients in severe cardiogenic shock – this can be caused by many disease that span multiple patient cohorts and pathways. Patients in cardiac arrest – cardiac arrest has an 8.6% survival in the UK. Our analysis has demonstrated there are around 300 patients a year in London who would benefit from access to ECMO and around 100 in the Thames Valley region. These patients have universally poor outcomes with current best practice and it is not unreasonable to suggest from our practice that 50% of these patients may survive if they had access to ECMO.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	VA ECMO if done correctly with proper patient selection and high quality service delivery can be a life saving treatment. There maybe unplanned benefits to the healthcare system through organ donation. Particularly in the arrested cohort sometimes patients recover all organ function but suffer devastating brain injuries. There are published case series demonstrating organ donation opportunities due to ECMO.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Cannulation for ECMO is a highly skilled procedure but one that healthcare providers from a wide range of backgrounds can be trained to do safely and effectively. There are systems around this world who perform pre hospital ECMO where they cannulate patients on the street. London Air Ambulance are planning to offer this service in the near future. Provided teams are adequately trained and resourced with appropriate equipment (cannulation and sterile equipment, ultrasound machines and probes and ECMO machines and circuits) then this procedure can be performed safely.

		To care for these patients there needs to be a proper network and system to identify patients and stabilise them. There needs to be enough ambulance transfer infrastructure to move patients to the most appropriate location. Once established on ECMO patients are likely best managed in a specialised intensive care unit appropriately resourced for this complex work with highly trained staff. These facilities already exist however it may be necessary to create more. Existing facilities may require funding for increased capacity and staffing to be able to cope with increased demand.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Extensive training is required to deliver VA ECMO safely. This training already exists in the NHS and could easily be rolled out nationally.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	VA ECMO is associated with a significantly increased risk of bleeding. Most patients treated with VA ECMO will have some degree of bleeding during the ECMO run. This can range between small amounts of manageable bleeding from the cannulation site through to life threatening haemorrhage or devastating intracerebral haemorrhage. The procedure carries a risk of vascular injury and ischaemic limb, these risks can be mitigated with techniques well described in the literature and in usual clinical practice such as adding a third cannula into the superficial femoral artery to perfuse the leg. Adverse events reported in ECMO-CS (circ 147 6 2023, 454-464): Bleeding – 31%, leg ischaemia 13.8%, stroke 5.2%, technical complications 1.7% Adverse events in ECLS Shock (NEJM 2023;389:1286-1297), bleeding 23%, limb ischaemia 11% In our experience we quote a 2.5% risk of fatal intracerebral haemorrhage. In our institution from April to today we have treated just over 100 patients with VA ECMO and have had the following complications that required definitive interventions: 1 ischaemic leg requiring fasciotomy, 1 ischaemic leg requiring repositioning a cannula, 1 cannula site bleeding requiring exploration, 1 displaced distal limb perfusion cannula requiring groin exploration, 1 x intra cerebral haemorrhage (non fatal), 2 major pulmonary bleeds, 1 failure to cannulate during cardiac arrest.

		On top of this there has been a lot of bleeding complications which we have managed conservatively, most patients do suffer some degree of bleeding.
14	Please list the key efficacy outcomes for this procedure/technology?	**Efficacy Outcomes:** Mortality at 3 months Survival to hospital discharge Neurological outcome 3 months post hospital discharge Quality of life at 6 months post hospital discharge **Quality outcomes** Transfusion Limb ischaemia ITU stay Hospital stay Time to cannulation (in ECPR)
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	VA ECMO carries a high risk of bleeding. This has to be balanced in the context of patient selection for this therapy. Due to this high risk it is only acceptable to use VA ECMO in patients who are most likely not to survive without it. These are patients in SCAI E shock or refractory cardiac arrest. The randomised data (as described in question 5) has not demonstrated clear and unequivocal benefit for VA ECMO. As described in that question however the trials do not really reflect current clinical practice and investigate a cohort known to be high risk (ACS-CS). Given the high risk nature of the treatment it is understandable that there are concerns around the paucity of randomised data showing benefit.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	The lack of high quality randomised data all though as described previously there is considerable nuance in interpreting the current published trials. In my opinion the main controversy in the NHS is the gross inequity of access to VA ECMO.

17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK. However – systems of care would need to be developed at regional levels that enabled rapid identification, stabilisation, escalation and transfer to these hospitals. Different regions may need to develop different solutions based on their individual geography.
18	Are people who are pregnant or have recently been pregnant eligible for VA ECMO for acute heart failure?	Yes – we have treated patients who are (or have recentely been) pregnant with VA ECMO and there are many cases reported in the literature. These have been patient with peri partum cardiomyopathy, critical ovarian hyperstimulation syndrome, pre exisiting cardiac disease and high risk delivery / section, decompensated pre exisiting dilated cardiomyopathy and amniotic fluid embolism.

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	We have presented our outcomes in multiple national and international conferences and have an article about how we improved the outcomes in our eCPR service currently under review in BMJ open quality. Presentations include – UK eCPR and VA ECMO experience at the UK ECPR summit in 2023. The manuscript of this study is nearly completed but not yet submitted to a journal. We would be happy to share. I have presented Harefield Hospital eCPR outcomes at EUROELSO 2023 and 2024 and our ECMO for cardiogenic shock outcomes at London Shock at the Royal Society of Medicine in 2024.
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	The ELSO registry is an international ECMO registry hosted in the USA. Most ECMO centres in the world submit data to this organisation.

		Within the UK ICNARC are trialling a cardiogenic shock module. We provide NHSBT with data on patients we treat with STMCS in the context of heart transplantation and mechanical circulatory support.
21	Please list any other data (published and/or unpublished) that you would like to share.	I am happy to share all of our local data as part of this work. We treat around 50 patients a year with VA ECMO in our hospital. We have spent considerable time refining our processes and selection criteria which resulted in us treating less patients with ECMO but making huge improvements in survival.

Other considerations

22	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	This is a surprisingly difficult question to answer as we do not understand the denominator for patients in cardiogenic shock. We know around 10% of patients presenting with STEMI to a heart attack centre are classified as being in cardiogenic shock but very few of these would be appropriate candidates for ECMO. We are referred around 20 patients a year from other hospitals with non ischaemic cardiogenic shock (often fulminant myocarditis, drug overdose or massive pulmonary embolism). Our referral area serves around 10million people. Our sister hospital (serving a similar size population) sees roughly the same numbers. We estimate around 300 patients a year in London may be candidates for ECPR. What I think it is reasonably to say is that VA ECMO is only beneficial on a tiny number of patients in the total population.
23	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.	Beneficial outcome measures: Survival – (survived ECMO, survived ITU, Survived hospital, survived 6 months) Neurological outcomes – Cerebral Performance Category Quality of life measures – standardised nationally but could include EQ5D, TSQ(for PTSD), MOCA (cognititve assessment). These should be measured in dedicated ICU follow up clinics at 6 months Adverse outcome measures: Measures of bleeding (transfusion rates is objective) Limb ischamia

	– Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	ITU LOS Hospital LOS Nosocomial infections Usual ICU quality metrics. **<u>Quality assurance:</u>** Review of patient selection Time from decision to starting ECMO Complications of cannulation, ITU management. Mobilisation and wakefulness on ECMO, sedative use. Time to escalation to medium / long term device.

Further comments

24	If you have any further comments (e.g. issues with usability or implementation, the need for further research), please describe.	Further research is always required, however we have seen over the last decade that the clinical service in STMCS has developed much more quickly that than the research has been able to support. RCTs have been published confirming elements of ECMO management that clinicians had already known to be the case years earlier. When dealing with these hypercritical cases it may be necessary to assess whatever data is available rather than rigidly relying on randomised trials.

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Declarations of interests

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Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	Speakers fees – Getinge	**March 2024**	
Direct - financial	Speakers Fees - Resuscitec	**October 2024**	
Direct - financial	Speakers Fees – Abiomed (now owned by Johnson and Johnson)	**February 2022**	

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

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

Print name:	**Click here to enter text. Alex Rosenberg**
Dated:	**Click here to enter text. 22/10/24**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

Name:	**Mr Harikrishna Doshi**
Job title:	**Consultant Cardiac and Transplant Surgeon**
Organisation:	**Golden Jubilee National University Hospital**
Email address:	[redacted]
Professional organisation or society membership/affiliation:	**Deputy Chair: Adult Cardiac Surgery subcommittee of Society of Cardiothoracic Surgery of Great Britain and Ireland (SCTS), Senior Clinical Lecturer (University of Glasgow)**
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	**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.

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	**I am practicing as Consultant Cardiac and Transplant surgeon at Golden Jubilee National University Hospital from November 2016. I am well versed with use of Veno-Arterial extra corporeal membrane oxygenation (VA ECMO) and have used it successfully in number of patients over the years of my practice.**
	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?	**I use ECMO routinely as treatment modality to treat patients with acute heart failure presenting with refractory cardiogenic shock. My understanding is that ECMO is routinely used by commissioned units across United Kingdom. There are 6 heart transplant centres where it is standard of care for treatment of patients with refractory cardiogenic shock following acute heart failure. There are growing number of centres in UK which are offering the service as a non-commissioned units along with the commissioned units but there also remains a wide disparity between demand and supply based on geographical location.**

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). I have done clinical research on this procedure involving patients or healthy volunteers. I have published this research. I have had no involvement in research on this procedure. Other (please comment) **As a part of my role as Deputy Chair of Adult Cardiac surgery subcommittee for Society of Cardiothoracic surgery of Great Britain and Ireland (SCTS), I have been tasked by the SCTS executive committee to draft Consensus statement on "Provision of Post Cardiotomy ECMO support at Non transplant Cardiac Surgical units across United Kingdom". I have been paired up with Prof George Krasopoulos (Consultant Cardiac Surgeon, Oxford Heart Centre & Hon. Professor in Cardiac Surgery and Clinical Governor for Oxford University Hospitals NHS FTP) for this task. The reason behind the project is the fact that recent times have witnessed significant increase in use of mechanical cardiac support (MCS) using ECMO in patients with cardiogenic shock. With publication of 2020 EACTS/ELSO/STS/AATS expert consensus statement, it was deemed appropriate that SCTS also clarifies its current position on use of post Cardiotomy ECMO (PC-ECMO) for non-cardiac transplant units across United Kingdom. As a part of the project, I have carried out extensive review of current literature and am well aware of its current use in the NHS. We have already created our initial draft and are now working to finalise the statement following discussions at Subcommittee's meetings.**
3	Does the title adequately reflect the procedure?	**I believe, that the title adequately reflects the procedure.**

	Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	**The current indication of VA ECMO remains largely as a 'bridge to cardiac transplantation'. This is due to funding/commissioning issues. It is important to understand the distribution of Cardiac surgical services across United Kingdom. There are 38 units performing adult cardiac surgery across United Kingdom (29 units in England, 3 units in Scotland, 2 units in Wales, 1 unit in Northern Ireland and 3 units in Republic of Ireland). Only 6 of these 38 units, carry out adult cardiac transplantation. VA ECMO is routinely used in Transplant centres but very few of non-transplant cardiac surgical units are commissioned for it use.** **We are seeing increasing use of ECMO for patients as a 'bridge to myocardial recovery' for example in patients with post cardiotomy cardiogenic shock or cardiogenic shock following primary PCI. Unfortunately, funding or commissioning around such indication is vague and thus needs clarity. Similarly, with increasing frequency, we are encountering patients, where adequate information is not available to make that decision, for example, patients presenting with 'Out of Hospital Cardiac arrest' (OOHCA). VA ECMO may be used in such patients as a 'bridge to decision'.** **In cardiac transplant centres, VA ECMO using centrifugal pump still remains most commonly used method for Mechanical Cardiac Support (MCS) following Intra-aortic balloon pump (IABP) however, other alternative devices such as Impella, are being used more frequently but they requires specialised surgical training and expertise.** 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.
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?	**No.**

5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	**With increasing use of ECMO, experience and expertise have grown. Principle element of ECMO is a centrifugal pump which has remained largely unchanged over many years but improved techniques, specialised cannulas, careful patient selection criteria, early identification of patients requiring ECMO and much improved intensive care management has led to improved outcomes.** **Careful consideration is required for selection actual techniques such as peripheral versus central ECMO. Techniques during cannulation for peripheral ECMO such as distal reperfusion lines or use of chimney grafts can lead to reduction in incidence of distal limb ischaemia. Use of newer devices such as Impella have been used successfully along with ECMO as Left ventricular unloading strategies (ECPELLA).** **ECMO carries inherently high complication rates such as bleeding, stroke, infection and thromboembolism etc. They may add to the problems which may have required ECMO in the first instance such as Cardiogenic shock. Increasing expertise has allowed better identification and management of complications. Regular core MDT team review and discussions are key in ensuring successful outcomes.**

Current management

6	Please describe the current standard of care that is used in the NHS.	**In our centre, our standard of care is early identification of patients. Core ECMO team consisting of 'Cardiac Transplant surgeon, anaesthetist/intensivists, heart failure cardiologist along with cardiac theatre team consisting of scrub nurses, theatre practitioners along with perfusionists' is mobilised early on. Timing from call out to institution of ECMO is carefully monitored and team works in tandem with group of clinicians who are managing the patients for example interventional cardiologists managing patients who has presented with cardiogenic shock following out of hospital cardiac arrest in cathlab. Expedited decision using core MDT team, decision to use what type of ECMO (peripheral versus central), cannulation techniques and use of heparinisation is discussed at the brief. Standard operating protocols (SOP) allows for team to anticipate and move quickly. Following each procedure we follow debrief techniques to learn and improve our techniques. Patient is handed over to ICU through a detailed handover and anticipated plan.**

		The decision to initiate and maintain PC-ECMO is complex and requires Multi-disciplinary discussion. In a non-transplant adult cardiac surgical units, very few Cardiac surgeons will have required surgical expertise for VA ECMO although cardiopulmonary bypass is routinely carried by them. Besides, management of VA ECMO patients requires concerted management from intensive care team and requires support from dedicated ECMO trained nurses. Management of anticoagulation strategy is also equally important and requires close discussion with surgical and intensive care team. Overall, management of VA ECMO patients is complex and resource intensive. The usual minimum recommendation for a team discussing the use of ECMO should be made up of a core group consisting of; **• Cardiac surgeon, usually with some experience of implantation of the ECMO** **• Anaesthetist facilitating the procedure,** **• Intensivist receiving the patient in the intensive care after the procedure,** **• Perfusionists trained in ECMO** **• Nurse from intensive care looking after the patient and proficient in looking after cases with ECMO.**
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	**There are many scientific reviews which supports use of Impella as an alternative device for use as mechanical cardiac support. Conventional ECMO still offers a reliable option which is already existing in most of the cardiac surgical units. Impella requires special surgical technique for use of 5 and 5.5 devices which requires cannulation through axillary artery. It requires regular assessment to ascertain positioning across aortic valve which requires reliable imaging and support from Cardiology service. There is an issue about cost comparison to conventional ECMO which does not require added investment along with durability of conventional VAD which may support patients for months.**

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?	**VA ECMO offers an invaluable circulatory and respiratory support tool for patients with refractory heart failure and cardiogenic shock.** **These is a lack of randomised control trial data support improved long term survival. 'Shock to survival: Framework to improve the care and outcome of people with**

		Cardiogenic shock' was published in October 2022 and is supported by the 'Association of cardiothoracic anaesthesia and critical care', 'Northern Ireland intensive care society' and 'Society of cardiothoracic surgery of great Britain and Ireland (SCTS)'. According to the report, observational data suggests that use of MCS can achieve acceptable survival rates especially in carefully selected patients before onset of multi organ failure (1) **Increasing recent use and growing expertise combined with improving technology has not transpired into improved survival in patients with post cardiotomy cardiogenic shock. In a recent large scale retrospective analysis involving more than 12,47,835 cardiac surgical patients from 2013 to 2018 in United States, post cardiotomy ECMO support was provided in 4475 (0.3%) patients with 42.1 % in hospital mortality and 26.6% patients survived to discharge (2). Recent retrospective, multicentre, observational Post-cardiotomy Extracorporeal life support (PEL-1) study provided an insight into outcomes of patients put on ECMO in the operation theatre as oppose to later in ICU or in-hospital in United states. Study included patients requiring PC-ECMO between years 2000 to 2020. It has shown that patients who require intraoperative as oppose to post-operative ECMO show different characteristics and outcomes. The study has concluded that post-operative ECMO is associated with higher complications, requirement for reoperations or percutaneous coronary interventions. They had higher in-hospital mortality (57.5% for intraoperative as oppose to 64.5%; p=0.002) for post-operative ECMO patients. Interestingly, the study also showed similar long-term survival between both groups (p=0.86) (3).** **1. Shock to Survival: a framework to improve the care and outcomes of people with cardiogenic shock in the UK. https://ics.ac.uk/static/8d541809-af1e-4e46-89c0d4382fd41bc6/Shock-to-Survival-Reportfinal.pdf** **2. Kakuturu J, Dhamija A, Chan E, Lagazzi L, Thibault D, Badhwar V, Hayanga JWA. Mortality and cost of post-cardiotomy extracorporeal support in the United States. Perfusion. 2023 Oct;38(7):1468-1477. doi: 10.1177/02676591221117355. Epub 2022 Aug 5. PMID: 35930658.** **3. Mariani S, Wang IW, van Bussel BCT, Heuts S, Wiedemann D, Saeed D, van der Horst ICC, Pozzi M, Loforte A, Boeken U, Samalavicius R, Bounader K, Hou X, Bunge JJH, Buscher H, Salazar L, Meyns B, Herr D, Matteucci S, Sponga S, Ramanathan K, Russo C, Formica F, Sakiyalak P, Fiore A, Camboni D, Raffa GM, Diaz R, Jung JS, Belohlavek J, Pellegrino V, Bianchi G, Pettinari M, Barbone A, Garcia JP, Shekar K, Whitman G,**

		Lorusso R; PELS-1 (PELS-1, Post-Cardiotomy Extracorporeal Life Support Study) Investigators. The importance of timing in postcardiotomy venoarterial extracorporeal membrane oxygenation: A descriptive multicenter observational study. J Thorac Cardiovasc Surg. 2023 Dec;166(6):1670-1682.e33. doi: 10.1016/j.jtcvs.2023.04.042. Epub 2023 May 17. PMID: 37201778.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	**Acute heart failure patients presenting with refractory cardiogenic shock following myocardial infarction, refractory arrhythmia, out of hospital cardiac arrest due to variety of causes constitutes bulk of patients. Acute valve pathologies, pulmonary embolism, myocarditis and hypothermia are some other indications.** **End stage heart failure patients and post heart surgery patients where there is Intraoperative failure to wean from cardiopulmonary bypass (CPB) because of ventricular failure or delayed refractory cardiogenic shock** **Postoperative cardiac arrest in the intensive care unit (ICU); respiratory failure; or intractable postoperative ventricular arrhythmias.** **Following heart transplant, ECMO is also used for early graft dysfunction in post-heart transplant recipients.** **ECMO is used in patients who develop right ventricular failure after LVAD implantation.**
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	**Yes. It can save lives.**
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	**It does not require special facilities but it can be carried out in any Cardiac surgical units across United Kingdom.** **Patients usually are associated with comorbidities which will have an impact on decision making about institution of ECMO as well as its on-going management. The goals of therapy are off loading the myocardium and/or lungs with an aim to use the MCS therapy as a bridge to recovery/transplant. Similarly, improving or maintaining end organ perfusion**

		is the key goal. Early discussion with regional Heart Transplant centre is essential as duration of ECMO support beyond a week is usually associated with increasing risk of catastrophic complications such as bleeding, embolization and cerebrovascular accidents (CVA). For patients who are not bridge to transplant or VAD therapy, early decision also allows strategies such as end of life pathways to be activated allowing peaceful and respectful farewell to the patient by the family. Optimal flows on ECMO requires careful consideration and discussion with perfusion team. Lot of centres allows heart to continue to eject which allows for better LV unloading, prevent intra cardiac stasis and clot formation and support weaning. Management of ECMO patients requires concerted management from intensive care team and requires support from dedicated ECMO trained nurses. Management of anticoagulation strategy is also equally important and requires close discussion with surgical and intensive care team. Overall, management of ECMO patients is complex and resource intensive. It requires multidisciplinary input with close collaboration with regional heart transplant teams.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	**Yes. As above.**

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	**-Neurological complications (Cerebral infarct, seizures, brain death, intracerebral haemorrhage) and Mortality** **Hou D, Wang H, Yang F, Hou X. Neurologic Complications in Adult Post-cardiotomy Cardiogenic Shock Patients Receiving Venoarterial Extracorporeal Membrane Oxygenation: A Cohort Study. Front Med (Lausanne). 2021. Aug 11;8:721774. doi: 10.3389/fmed.2021.721774** **- Major haemorrhage (might requiring reopening) and Renal failure requiring Renal Replacement Therapy (RRT).** **Khorsandi M, Dougherty S, Sinclair A, et al. A 20-year multicentre outcome analysis of salvage mechanical circulatory support for refractory cardiogenic shock after cardiac surgery. 2016. Nov 8;11(1):151. doi: 10.1186/s13019-016-0545-5**

		-Limb ischemia **Charbonneau F, Chahinian K, Bebawi E, et al. Parameters associated with successful weaning of veno-arterial extracorporeal membrane oxygenation: a systematic review. Crit Care. 2022. Dec 5;26(1):375. doi: 10.1186/s13054-022-04249-w**
14	Please list the key efficacy outcomes for this procedure/technology?	**Number of lives saved.** **Rate of successful ECMO wean and ECMO explant** **Time from ECMO implant to explant** **Time to discharge home** **Ventricular function recovery over time** **30 day and 1 year and 5 years survival**
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	**Rate of vascular/bowel/kidney complications with or without need for surgical intervention(LL NIRS monitoring)** **Rate of reoperation for bleeding/tamponade** **Rate of infection** **Rate of ECMO circuit complications/changes prior to explant** **Stroke/TIAs** **End organ failure** **Mortality (30 day/1 year)**
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	

17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	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.
18	Are people who are pregnant or have recently been pregnant eligible for VA ECMO for acute heart failure?	**According to an international multicentre retrospective study, ECMO is associated with significant maternal and foetal risks. However, we have to bear in mind that when pregnant mother presents with acute heart failure and reaches stage of refractory cardiogenic shock, without use of ECMO, the maternal and foetal risks are almost 100%. In that respect, the report suggest that for peri partum VA ECMO, maternal survival was 71% and from overall cases, foetal survival was 73% (Malfertheiner SF, Brodie D, Burrell A, Taccone FS, Broman LM, Shekar K, Agerstrand CL, Serra AL, Fraser J, Malfertheiner MV. Extracorporeal membrane oxygenation during pregnancy and peripartal. An international retrospective multicenter study. Perfusion. 2023 Jul;38(5):966-972. doi: 10.1177/02676591221090668. Epub 2022 May 13. PMID: 35549557; PMCID: PMC10265280.).**

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help	**1. Lorusso R, Whitman G, Milojevic M, Raffa G, McMullan DM, Boeken U, Haft J, Bermudez CA, Shah AS, D'Alessandro DA. 2020 EACTS/ELSO/STS/AATS expert consensus on post-cardiotomy extracorporeal life support in adult patients. Eur J Cardiothorac Surg. 2021 Jan 4;59(1):12-53. doi: 10.1093/ejcts/ezaa283. PMID: 33026084.** **2. Bellumkonda L, Gul B, Masri SC. Evolving concepts in diagnosis and management of cardiogenic shock. Am J Cardiology; 2018;122:1104.** **3. Lorusso R, Raffa GM, Alenizy K, Sluijpers N, Makhoul M, Brodie D, et al. Structured review of post-cardiotomy extracorporeal membrane oxygenation: part 1—adult patients. J Heart Lung Transpl. 2019;38:1125-1143** **4. Fukuhara S, Takeda K, Garan AR, Kurlansky P, Hastie J, Naka Y, et al. Contemporary mechanical circulatory support therapy for postcardiotomy shock. Gen Thorac Cardiovasc Surg. 2016;64:183-191.**

	us if you list any that you think are particularly important.	**5. Stretch R, Sauer CM, Yuh DD, Bonde P. National trends in the utilization of short-term mechanical circulatory support: incidence, outcomes, and cost analysis. J Am Coll Cardiol. 2014;64:1407-1415.** **6. Whitman GJR. Extracorporeal membrane oxygenation for the treatment of postcardiotomy shock. J Thorac Cardiovasc Surg 2017;153:95-101.** **7. Haft JW. Temporary mechanical circulatory support for postcardiotomy shock: don't come late to the party. J Thorac Cardiovasc Surg 2015;149:1451-2.** **8. Pokersnik JA, Buda T, Bashour CA, Gonzalez-Stawinski GV. Have changes in ECMO technology impacted outcomes in adult patients developing postcardiotomy cardiogenic shock? J Card Surg 2012;27:246-52.** **9. Kakuturu J, Dhamija A, Chan E, Lagazzi L, Thibault D, Badhwar V, Hayanga JWA. Mortality and cost of post-cardiotomy extracorporeal support in the United States. Perfusion. 2023 Oct;38(7):1468-1477. doi: 10.1177/02676591221117355. Epub 2022 Aug 5. PMID: 35930658.** **10. Mariani S, Wang IW, van Bussel BCT, Heuts S, Wiedemann D, Saeed D, van der Horst ICC, Pozzi M, Loforte A, Boeken U, Samalavicius R, Bounader K, Hou X, Bunge JJH, Buscher H, Salazar L, Meyns B, Herr D, Matteucci S, Sponga S, Ramanathan K, Russo C, Formica F, Sakiyalak P, Fiore A, Camboni D, Raffa GM, Diaz R, Jung JS, Belohlavek J, Pellegrino V, Bianchi G, Pettinari M, Barbone A, Garcia JP, Shekar K, Whitman G, Lorusso R; PELS-1 (PELS-1, Post-Cardiotomy Extracorporeal Life Support Study) Investigators. The importance of timing in postcardiotomy venoarterial extracorporeal membrane oxygenation: A descriptive multicenter observational study. J Thorac Cardiovasc Surg. 2023 Dec;166(6):1670-1682.e33. doi: 10.1016/j.jtcvs.2023.04.042. Epub 2023 May 17. PMID: 37201778.**
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	**As above**
21	Please list any other data (published and/or unpublished) that you would like to share.	**External validation of the PC-ECMO score in postcardiotomy veno-arterial extracorporeal membrane oxygenation. Biancari F, Juvonen T, Cho SM, Hernández Pérez FJ, L'Acqua C, Arafat AA, AlBarak MM, Laimoud M, Djordjevic I, Samalavicius R, Alonso-Fernandez-Gatta M, Sahli SD, Kaserer A, Dominici C, Mäkikallio T. Int J Atif Organs. 2024 Apr;47(4):313-317. doi: 10.1177/03913988241237701. Epub 2024 Mar 10. PMID: 38462690**

		Extracorporeal Membrane Oxygenation in Postcardiotomy Cardiogenic Shock. Akbik B, Chou LP, Gorthi J. Methodist Debakey Cardiovasc J. 2023 Aug 1;19(4):66-73. doi: 10.14797/mdcvj.1256. eCollection 2023. PMID: 37547900 **2020 EACTS/ELSO/STS/AATS Expert Consensus on Post-Cardiotomy Extracorporeal Life Support in Adult Patients Roberto Lorusso, MD, PhD, Chairperson, Glenn Whitman, MD, Chairperson, Milan Milojevic, MD, PhD, Giuseppe Raffa, MD, PhD, David M. McMullan, MD, Udo Boeken, MD, PhD, Jonathan Haft, MD, Christian A. Bermudez, MD, Ashish S. Shah, MD, and David A. D'Alessandro, MD. Ann Thorac Surg 2021;111:327-69 0003-4975, https://doi.org/10.1016/j.athoracsur.2020.07.009** **Long-term outcomes of extracorporeal membrane oxygenation support for postcardiotomy shock Shao-Wei Chen MD, Feng-Chun Tsai MD, Yu-Sheng Lin MD, Chih-Hsiang Chang MD, Dong-Yi Chen MD, An-Hsun Chou MD, PhD, Tien-Hsing Chen MD The Journal of Thoracic and Cardiovascular Surgery. Volume 154, Issue 2, August 2017, Pages 469-477.e2**

Other considerations

22	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	**There is no central registry in UK for use of VA ECMO but according to an old published report (Specialised Commissioning Team NHS England. Clinical Commissioning Policy: Extra corporeal membrane oxygenation (ECMO) service for adults with cardiac failure. www.england.nhs.uk/commissioning/wp/content/uploads/sites/12/2016/07/16028_FINAL.pdf), it was estimated that case load will be around 200 cases per annum but there is a significant increase in numbers.** **According to November 2023 NHSBT annual report on use of mechanical circulatory support (MCS) related to heart transplantation, 112 patients underwent heart transplantation from short term MCS. Of these, 53 patients received heart transplant from ECMO support. Similarly, in the year 2022-23, 52 patients required mechanical cardiac support following heart transplantation and severe primary graft dysfunction, comprising 42 patients requiring ECMO and 8 patients requiring VAD+ECMO. Thus in year 2022-23 alone, 113 patients were**

		either transplanted from ECMO or required ECMO support following heart transplant surgery (nhsbt-mechanical-circulatory-support-report-2223.pdf). **There are increasing numbers of added patients who require ECMO for various indications mentioned above.**
23	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: **Number of lives saved.** **Rate of successful ECMO wean and ECMO explant** **Time from ECMO implant to explant** **Time to discharge home** **Ventricular function 30 days** **30 day and 1 year and 5 years survival** Adverse outcome measures: **Rate of vascular/bowel/kidney complications with or without need for surgical intervention(LL NIRS monitoring)** **Rate of reoperation for bleeding/tamponade** **Rate of infection** **Rate of ECMO circuit complications/changes prior to explant** **Stroke/TIAs** **End organ failure** **Mortality (30 day/1 year)**

Further comments

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

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Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
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:	**Mr Harikrishna Doshi**
Dated:	**21/11/2024**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

Name:	Paul Exton
Job title:	Lead Perfusionist (ECMO)
Organisation:	Manchester University Foundation NHS Trust
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Society of Clinical Perfusion Scientists of GB&
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	Click here to enter text.

How NICE will use this information:

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

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I have worked with ECMO for 18 years and been the Perfusion lead for the service for 8 years. I am fully conversant with both cardiac (VA) and respiratory ECMO (VV) as well as it's hybrid use in cardiac theatres for procedures such as lung transplantation, complex thoracic procedures and in the Cath lab for complex PCI / EP cases.
	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?	We use it every day and are key stakeholders as part of the ECMO MDT. ECMO could need to be used in every cardiothoracic department in a post cardiotomy scenario or during / after complex thoracic or cardiology procedures. In non-transplant / respiratory ECMO centres, this offers significant challenges in regard to experience with the technique and patient, management, as well as the disruption to elective case delivery. In established transplant / respiratory ECMO centres, the elective, rather than salvage use of these techniques has greatly increased. This is due to the MDT approach to the care of patients on ECMO and the development and training of ECMO nurses and co-ordinators to allow for the

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	delivery of the service on ICU and the preservation of elective services. This has led to it's use by cardiac, thoracic and cardiology services. As Perfusionists, we deal with the delivery not the patient selection
Re	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	YES Established practice and no longer new. .
4	Does this procedure/technology have the potential to replace current standard care, or would it be used as an addition to existing standard care?	In Addition to existing standard care

5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No No

Current management

6	Please describe the current standard of care that is used in the NHS.	Patients with acute heart failure would be treated with inotropes, then with an IABP before reaching a ceiling of care for mechanical support. In cardiothoracic transplant units, patients would be selected for VA ECMO based on established criteria and cannulated either in theatre or bedside on ICU, dependant on clinical urgency. In non-cardiothoracic transplant centres, patients would need to be referred to a specialist centre, or cannulated (if an emergency/urgent) and then request a cardiothoracic transplant centre to mobilise and transfer the patient. In rare cases a local referring hospital may request that an ECMO team mobilise and put the patient on VA ECMO and transfer to the specialist centre.

7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	An Impella (ABIOMED) device may suffice as a bridge to decision in some acute cardiogenic shock cases.

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?	Prevention of multiorgan failure for patient's that may be suitable for long term implantable VAD.s or as a bridge to BIVAD / heart transplant
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Patients with acute heart failure that have reached a ceiling of care and are suitable for a destination therapy (VAD / Transplant)
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Unsure, with enough ICU and ward beds, more patients with heart failure may a physiological benefit and potentially make it to be listed for destination therapies such as VAD / transplant
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	In non-cardiothoracic transplant / VV ECMO centres: Sufficient ECMO equipment (long term centrifugal pumps / long term oxygenators / ECMO heater coolers / gas blenders / ECMO carts), ECMO cannulae, Dedicated ICU (with ECMO MDT staff), Perfusion department staffed to cope with the extra workload and training of nursing staff. In cardiothoracic transplant / VV ECMO centres: More of the equipment they already have, more staff to oversee the increased demand and of course…. More beds to cope with the demand
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	In cardiothoracic transplant / VV ECMO centres: not much (except for training new staff) In non-cardiothoracic transplant / VV ECMO centres: lots!

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Vascular damage / cerebral bleed / GI Bleed / DIC / Intra vessel thrombus / infection / stroke / air embolus
14	Please list the key efficacy outcomes for this procedure/technology?	
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	??
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Just in patient selection
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	. Fewer than 10 specialist centres in the UK.
18	Are people who are pregnant or have recently been pregnant eligible for VA ECMO for acute heart failure?	Yes

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list, but it will help us if you list any that you think are particularly important.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	
21	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

22	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)?	100-200?
23	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	Beneficial outcome measures: Survival / bridge to recovery / bridge to HM3 / bridge to transplant

	outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. – Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Adverse outcome measures: Cerebral bleed / GI Bleed / death / stroke / vascular damage / infection / intravascular thrombus / DIC

Further comments

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

NICE National Institute for Health and Care Excellence

Declarations of interests

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

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

☒ 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:	**Paul Exton**
Dated:	**12/12/2024**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

Name:	Dr Sameer Patel
Job title:	Consultant in Intensive Care, Liver Intensive Care & ECMO
Organisation:	King's College Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Medical Defence Union (MDU), Faculty of Intensive Care Medicine (FICM), Intensive Care Society (ICS), European Society of Intensive Care Medicine (ESICM), Royal College of Anaesthetistsd, Royal College of Physicians, European Respiratory Society, International Liver Transplant Society, European Association for the Study of Liver Diseases
Nominated/ratified by (if applicable):	Professor Julia Wendon
Registration number (e.g. GMC, NMC, HCPC)	GMC 6078736

How NICE will use this information:

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology?	I am familiar with the use of veno-arterial ECMO. I have been a consultant in ECMO for 10 years with more than 14 years clinical experience with its use. I am the current ECMO Clinical Lead for my Trust.
	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	I have been using VA-ECMO for a variety of indications for 14 years (initially through my training) and in particular for the last 10 years as a consultant in ECMO at King's College Hospital. VA ECMO is currently utilised by all the commissioned respiratory V-V ECMO centres, and a number of cardiac centres across the country. In London it's use is common in 5 centres (Barts, Harefield, Royal Brompton, King's and GSTT) and is soon going to be used by St George's and Hammersmith Hospitals. Outside London it is already in use at Papworth, Wythenshawe, Glenfield and Freeman Hospital, Newcastle, and has recently been used at Bristol Royal Infirmary. There may be a handful of other cardiac centres using ECMO specifically to support patients post cardiac surgery but I do not know which. Clinicians typically involved in its use are Intensive Care Physicians who manage these patients in the ICU and are the primary specialty involved as a result. Cardiothoracic surgeons and cardiologists are also involved in patient selection and potentially initial implantation in theatre or

	specialty for this procedure/technology, please indicate your experience with it.	the cath lab respectively (rarely they also be ECMO consultants managing the patient on ecmo on a day to day basis). Outside of the UK, Emergency Department physicians are also involved. The majority of patients will be managed within my own centre and the same applies for most other centres utilising VA ECMO. Referral to another centre only typically occurs if a patient is already on VA ECMO but is unable to be weaned from ECMO, and therefore is considered to require bridge to another medium to long term device such as a VAD, or for consideration of a heart transplant. These patients are subsequently referred to heart and lung transplant centres.
2	– Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done clinical research on this procedure involving patients or healthy volunteers – PI for EuroSHOCK Trial, and PI for HERACLES studies. I have published research of use of ECMO peri liver transplantation and have papers in progress relating to ECPR in the UK.
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	It is a reasonable title but an alternative one could also be **Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for cardiogenic shock in adults** Yes – but perhaps a broader term might be as highlighted in title above. Either would be acceptable however Established practice and no longer new based on international management of such cases. Within established centres the same would be considered true. It is not a standard of care and therefore not likely to be adopted in all ICUs but I would expect a handful more tertiary centres to want to deliver this in the UK.

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 would be used in addition to standard of care and be limited to tertiary centres with the appropriate multidisciplinary expertise. There is a possibility of a hub and spoke model with some centres wishing to establish appropriate patients on VA ECMO but then transfer them for ongoing management to a centre capable of doing so. A variation of this practice already exists where ECMO centres will go to non-ECMO centres to establish patients on ECMO and then retrieve them back to their own centre.
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	Technology has significantly improved over the last 40-50 years. Current devices are small and compact and familiarity and expertise in managing these devices has improved. In particular the degree of anticoagulation required to prevent circuit loss from thrombosis has reduced, thus reducing complications such as bleeding risk. The evidence base continues to demonstrate that in appropriately selected patients ECMO survival is improving. There are a variety of indications, and thus there are some differences in outcomes based on underlying aetiology, with some having more benefit than others e.g. myocarditis versus post cardiotomy cardiogenic shock. However, in all indications outcomes are generally improving.

Current management

6	Please describe the current standard of care that is used in the NHS.	The current standard of care is to admit patients with acute heart failure to the Coronary Care Unit, or more typically the Intensive Care Unit. These patients may be in varying degrees of shock and therefore the degree of support required will depend on the severity of shock and progression into multiorgan failure. Broadly speaking management will focus on reversing the cause of the shock whilst providing cardiac or cardiorespiratory support using pharmacological interventions such as vasopressors and inotropes +/- simple mechanical circulatory support devices such as

		intra-aortic balloon pumps. More recently and in particular for those in acute heart failure secondary to myocardial infarction the use of microaxial flow pumps such as Impella are being utilised. This is likely to increase given the recent DanGer Shock RCT Trial publication in NEJM. Patients are highly likely to be mechanically ventilated and on renal replacement therapy particularly for more severe cases.
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	Other mechanical circulatory devices do exist and do have a role in specific scenarios in this patient group (see above for IABP and Impella). However, these devices are not adequate to support patients who have progressed from isolated cardiogenic shock/acute heart failure to multiorgan failure. In these scenarios VA ECMO is superior and the only MCS device applicable as it has the ability to provide oxygenated blood which the other devices do not. IABP provides support by reducing afterload and incorporates a balloon that inflates in diastole and deflates in systole and reduces myocardial work whilst improving coronary perfusion. Impella and other microaxial flow devices withdraw blood directly from the left ventricle and eject it into the aorta, thereby reducing LV distension (unload the LV). They too reduce myocardial work

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?	VA ECMO represents an advanced organ support modality that buys additional time for myocardial recovery whilst providing oxygenated blood to be delivered to the major organs of the body.
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	Ischaemic cardiomyopathy i.e. post myocardial infarction cardiogenic shock/acute heart failure Post massive pulmonary embolism Failure to wean from cardiac bypass in patients undergoing major cardiac surgery Drug overdoses resulting in cardiac toxicity e.g. beta blocker overdose Acute decompensation of non-ischaemic heart failure (multiple causes here) Bridge to VAD or heart transplant Blunt trauma Possibly penetrating trauma but paucity of data in this group Refractory cardiac arrest requiring extracorporeal cardiopulmonary resuscitation (ECPR)
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	Yes. This is a high mortality group (40-50% for those in severe cardiogenic shock/acute heart failure who are in progressive multiorgan failure) and has the ability to improve outcomes in a select group of patients. This is borne out in several observational studies but less so in RCTs in some select indications e.g. for acute myocardial infarction.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	Need appropriate sized ICU capable of admitting and managing these patients with access to appropriate teams, but other than that no specific changes to facilities are required.
12	Is any specific training needed in order to use the procedure/technology with respect to efficacy or safety?	Yes. Need appropriately trained ECMO consultants, nurses and perfusionists to manage these patients. Formal training is required e.g. ELSO accreditation process or training within established

		ECMO centres. Training incorporates theoretical knowledge, hands on pump hours (proctorship), an exam and ongoing regular simulation and training according to strict governance processes.

Safety and efficacy of the procedure/technology

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence: Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	Harms include increased myocardial work (if have not unloaded the LV with another device), bleeding complications (cannula site related but also intracranial bleed) relating to anticoagulation, infection, inability to wean from ECMO, vascular complications (secondary to large bore devices in femoral artery). Patients can also develop DVT and ischaemic strokes. Bleeding risk 10-30% in VA ECMO CNS bleed 1-5% CNS ischaemic stroke 1-8% Thromboembolic complications 15-30% Arteriovenous fistula or pseudoaneurysm needing a surgical repair <5% Vascular complications 10-12% Infection 10-15% Harlequin syndrome
14	Please list the key efficacy outcomes for this procedure/technology?	Bridge to Survival – patient established on ECMO buying time for heart to recover and then weaning off VA ECMO Bridge to destination device e.g. VAD – for those with inability to wean from VA ECMO but meeting criteria for VAD to allow longer duration to establish recovery of heart function Bridge to heart transplantation – for those with end stage heart disease
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Concerns relate to exact timing and indications for use of ECMO for different conditions. Greatest uncertainty is for acute myocardial infarction where RCT evidence has been less supportive of its use. However these trials were in highly select groups within the AMI population and therefore not representative of the population as a whole.

16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Only uncertainty relates to choice of LV unloading device required if using peripheral VA ECMO i.e. IABP or impella in association with ECMO No RCTs for VA ECMO in non-ischaemic cardiogenic shock
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	A minority of hospitals, but at least 10 in the UK – tertiary
18	Are people who are pregnant or have recently been pregnant eligible for VA ECMO for acute heart failure?	Yes

Abstracts and ongoing studies

19	Please list any abstracts or conference proceedings that you are aware of that have been recently presented / published on this procedure/technology (this can include your own work). Please note that NICE will do a comprehensive literature search; we are only asking you for any very recent abstracts or conference proceedings which might not be found using standard literature searches. You do not need to supply a comprehensive reference list but it will help us if you list any that you think are particularly important.	Shock to Survival Cardiogenic Shock, Lancet 2024
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	Registry Data- ELSO Registry – largest ECMO database in the world No registries of CS in the UK for MCS use or patient outcomes
21	Please list any other data (published and/or unpublished) that you would like to share.	

Other considerations

22	Approximately how many people each year would be eligible for an intervention with this procedure/technology, (give either as an estimated number, or a proportion of the target population)?	5-10% of cardiogenic shock patients
23	Please suggest potential audit criteria for this procedure/technology. If known, please describe: − Beneficial outcome measures. These should include short- and long-term clinical outcomes, quality-of-life measures and patient-related outcomes. Please suggest the most appropriate method of measurement for each and the timescales over which these should be measured. − Adverse outcome measures. These should include early and late complications. Please state the post procedure timescales over which these should be measured:	Beneficial outcome measures: 30, 90, 180, day survival 1 year outcome VA ECMO survival (wean from ECMO) Echo parameters on weaning and at 6 months: LV and RV dimensions and function including diastolic function (follow British Society of Echocardiography guidelines for a comprehensive dataset) Quality of life measures: EQ-5D-5L questionnaire, SF-36 score Adverse outcome measures: Bleeding rate CNS bleed CNS ischaemic stroke Thromboembolic complications Arteriovenous fistula or pseudoaneurysm needing a surgical repair Vascular complications Infection Harlequin syndrome

Further comments

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

NICE National Institute for Health and Care Excellence

Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Non-financial professional	London Cardiogenic Shock Board Member	**Feb 2024**	**Feb 2027**
Non-financial professional	London ECPR Consortium Board Member	**Jan 2022**	**Ongoing**
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:	**SAMEER PATEL**
Dated:	**24th November 2024**

NICE National Institute for Health and Care Excellence

Professional Expert Questionnaire

Technology/Procedure name & indication: IP1071/2 Venoarterial Extracorporeal membrane oxygenation (VA ECMO) for acute heart failure in adults

Your information

Name:	Stephen Pettit
Job title:	Consultant Cardiologist
Organisation:	Royal Papworth Hospital
Email address:	[redacted]
Professional organisation or society membership/affiliation:	Click here to enter text.
Nominated/ratified by (if applicable):	Click here to enter text.
Registration number (e.g. GMC, NMC, HCPC)	6052477

How NICE will use this information:

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

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

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

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

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

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

Click here to enter text.

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

1	Please describe your level of experience with the procedure/technology, for example: Are you familiar with the procedure/technology? Have you used it or are you currently using it? – Do you know how widely this procedure/technology is used in the NHS or what is the likely speed of uptake? – Is this procedure/technology performed/used by clinicians in specialities other than your own?	I am consultant cardiologist and clinical lead of the cardiothoracic transplant service at Royal Papworth Hospital. I deal with all forms of mechanical circulatory support (MCS) on a regular basis, including both peripheral and central VA ECMO. We are only commissioned to use MCS as a bridge to heart transplantation. We use peripheral VA ECMO in patients with acute heart failure around 1-2 times per year on average (16 runs over last decade). Our institution prefers to use other forms of MCS whenever possible because adverse event rates are lower and potential duration of support is longer. This is important given the length of time that it takes to find a suitable donor heart. The technical aspects of the placing patients on VA ECMO are typically performed by intensive care doctors or cardiac surgeons.

	− If your specialty is involved in patient selection or referral to another specialty for this procedure/technology, please indicate your experience with it.	
2	− Please indicate your research experience relating to this procedure (please choose one or more if relevant):	I have done bibliographic research on this procedure. I have done research on this procedure in laboratory settings (e.g. device-related research). **I have done clinical research on this procedure involving patients or healthy volunteers.** **I have published this research.** I have had no involvement in research on this procedure. Other (please comment)
3	Does the title adequately reflect the procedure? Is the proposed indication appropriate? If not, please explain. How innovative is this procedure/technology, compared to the current standard of care? Is it a minor variation or a novel approach/concept/design? Which of the following best describes the procedure (please choose one):	Yes. The technique is not innovative and has been widely used around the world for the last 20 year. There have been a number of randomised controlled trials involving VA ECMO in the last 5 years, most of which have not showed benefit to routine use of VA ECMOP **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.

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?	Addition
5	Have there been any substantial modifications to the procedure technique or, if applicable, to devices involved in the procedure? Has the evidence base on the efficacy and safety of this procedure changed substantially since publication of the guidance?	No substantial modifications There have been several important randomised controlled trials published in the last couple of years. ECLS SHOCK https://www.nejm.org/doi/full/10.1056/NEJMoa2307227 EURO SHOCK https://pubmed.ncbi.nlm.nih.gov/37334659/ ECMO CS https://pubmed.ncbi.nlm.nih.gov/36335478/ ANCHOR (suspended) https://clinicaltrials.gov/study/NCT04184635

Current management

6	Please describe the current standard of care that is used in the NHS.	There is no current standard of care for management of cardiogenic shock in the NHS https://ics.ac.uk/resource/shock-to-survival-report.html
7	Are you aware of any other competing or alternative procedure/technology available to the NHS which have a similar function/mode of action to this? If so, how do these differ from the procedure/technology described in the briefing?	The main competing technology is the Impella family of percutaneous ventricular assist devices

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?	Survival
9	Are there any groups of patients who would particularly benefit from using this procedure/technology?	The very sickest patients with cardiogenic shock who are either (a) potential candidates for heart transplantation or (b) have reasonable expectation of heart recovery in days/weeks.
10	Does this procedure/technology have the potential to change the current pathway or clinical outcomes to benefit the healthcare system? Could it lead, for example, to improved outcomes, fewer hospital visits or less invasive treatment?	There is definitely potential to change the current pathway for patients with cardiogenic shock. If the technology was introduced in a co-ordinated fashion, then it could improve standards of care for all patients with cardiogenic shock.
11	What clinical facilities (or changes to existing facilities) are needed to do this procedure/technology safely?	The procedure is already being done in around 10 cardiac surgical units in the UK.
12	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

13	What are the potential harms of the procedure/technology? Please list any adverse events and potential risks (even if uncommon) and, if possible, estimate their incidence:	Too numerous to list here, up to and including life/limb-threatening adverse events. Serious adverse events relating to peripheral VA ECMO are also universal if support is required for more than one week.

	Adverse events reported in the literature (if possible, please cite literature) Anecdotal adverse events (known from experience) Theoretical adverse events	
14	Please list the key efficacy outcomes for this procedure/technology?	Survival to discharge, 1-year survival, QOL at 1 year.
15	Please list any uncertainties or concerns about the efficacy and safety of this procedure/?	Huge uncertainties. See trials above – there is good evidence that routine of VA ECMO does not improve clinical outcomes. However, the sickest patients – those that would die immediately without VA ECMO support, are never included in these trials.
16	Is there controversy, or important uncertainty, about any aspect of the procedure/technology?	Yes.
17	If it is safe and efficacious, in your opinion, will this procedure be carried out in (please choose one):	Most or all district general hospitals. **A minority of hospitals, but at least 10 in the UK.** Fewer than 10 specialist centres in the UK. Cannot predict at present.
18	Are people who are pregnant or have recently been pregnant eligible for VA ECMO for acute heart failure?	Yes

Abstracts and ongoing studies

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

	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.	
20	Are there any major trials or registries of this procedure/technology currently in progress? If so, please list.	ANCHOR
21	Please list any other data (published and/or unpublished) that you would like to share.	There is data in the ELSO registry and UK VAD database

Other considerations

22	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)?	A tiny number – probably fewer than 100-200 per year in the UK.
23	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.	Beneficial outcome measures: Outcome from VA ECMO: recovery, death, transplant, transition to alternate form of MCS Survival to discharge Survival at one year QOL at one year Adverse outcome measures: Use definitions in the ELSO registry https://www.elso.org/registry/supportdocuments/eclscomplicationscode.aspx

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

Further comments

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

NICE National Institute for Health and Care Excellence

Declarations of interests

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

Type of interest *	Description of interest	Relevant dates	
		Interest arose	Interest ceased
Direct - financial	I am a member of the Abbott UK heart failure advisory board	**2023**	
Direct - financial	I have been to educational events supported by AbioMed	**2024**	
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:	**Stephen Pettit**
Dated:	**26-Oct-2024**