NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

VA ECMO for postcardiotomy cardiogenic shock in adults

Postcardiotomy refers to the period immediately after open-heart surgery.

Postcardiotomy cardiogenic shock is when the heart cannot pump blood well enough to meet the body's needs. It is rare and life threatening.

Venoarterial extracorporeal membrane oxygenation (VA ECMO) is when blood is taken out of the body and put through an artificial pump and lung located outside the body (extracorporeal). The ECMO machine adds oxygen to the blood (oxygenation), removes carbon dioxide and pumps the blood around the body. Tubes take the blood out of a large vein and return it into a large artery (venoarterial). This is done over days or weeks. The aim is to provide oxygenated blood to the body, while the heart, or heart and lungs, recover, or as a bridge to a treatment.

Guidance development process

NICE interventional procedures guidance evaluates procedures used for treatment or diagnosis. It provides evidence-based recommendations about how safe and efficacious these procedures are. The guidance supports healthcare professionals and commissioners to ensure that patients get the best possible care. By reviewing clinical evidence and considering patient outcomes, NICE aims to improve patient safety and treatment choices in the NHS.

Find out more on the NICE webpage on interventional procedures guidance.

NICE is producing this guidance on VA ECMO for postcardiotomy cardiogenic shock in the NHS. The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

Guidance – VA ECMO for postcardiotomy cardiogenic shock in adults

Page 1 of 9

Issue date: September 2025

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This document has been prepared for consultation with the

stakeholders. It summarises the evidence and views that have been

considered, and sets out the recommendations made by the committee. NICE

invites comments from the stakeholders for this evaluation and the public.

This document should be read along with the evidence.

The committee is interested in receiving comments on the following:

Has all of the relevant evidence been taken into account?

Are the summaries of efficacy reasonable interpretations of the evidence?

Are the recommendations sound and a suitable basis for guidance to the

NHS?

Are there any aspects of the recommendations that need particular

consideration to ensure we avoid unlawful discrimination against any group

of people on the grounds of age, disability, gender reassignment,

pregnancy and maternity, race, religion or belief, sex or sexual orientation?

After consultation:

Based on the consultation comments received, the committee may meet

again.

If committee meets again it will consider the evidence, this evaluation

consultation document and comments from stakeholders.

The committee will then prepare the final draft guidance, which will go

through a resolution process before the final guidance is agreed.

Note that this document is not NICE's final guidance on VA ECMO for

postcardiotomy cardiogenic shock. The recommendations in section 1

may change after consultation.

More details are available in NICE's interventional procedures programme

manual.

Key dates:

Closing date for comments: 23 October 2025

1 Recommendation

1.1 Venoarterial extracorporeal membrane oxygenation (VA ECMO) can be used in the NHS during the evidence generation period as an option to manage postcardiotomy cardiogenic shock (PCS) in adults. There must be enhanced informed consent and auditing of outcomes.

What this means in practice

There are uncertainties around the safety and efficacy of VA ECMO to manage PCS. It could be used if needed while more evidence is generated.

After this, this guidance will be reviewed and the recommendations may change.

Healthcare professionals do not have to offer this procedure and should discuss the available options with the person with PCS (and their family and carers as appropriate) before a joint decision is made, if possible.

Hospital trusts will have their own policies on funding procedures and getting permission to do operations and monitoring results. NHS England may also have policies on funding of procedures.

Enhanced informed consent

Because there are uncertainties about whether this procedure is safe and efficacious, there must be an emphasis on informed consent when possible. Healthcare professionals, when possible, must make sure that people (and their families and carers as appropriate) understand the uncertainty and lack of evidence around a procedure's safety and efficacy using NICE's information for the public. Healthcare professionals must also inform the clinical governance leads in their organisation if they want to do the procedure.

Guidance – VA ECMO for postcardiotomy cardiogenic shock in adults

Page 3 of 9

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Auditing of outcomes

Healthcare professionals doing this procedure should collect data on safety and outcomes of the procedure. Enter details about everyone having this procedure into the Extracorporeal Life Support Organization registry and

regularly review the data on outcomes and safety.

Who should be involved with the procedure

Patient selection should be done by a suitably constituted multidisciplinary team. The procedure could be done in centres specialising in managing

PCS and by healthcare professionals with specific training in this

procedure.

What evidence generation is needed

Healthcare professionals must collect data specifically around the safety and efficacy of this procedure, including on:

patient selection

the technology used

short- and long-term survival outcomes

complication rates.

Why the committee made this recommendation

Some people with PCS do not survive being taken off a cardiopulmonary bypass machine after cardiac surgery. Evidence from observational studies suggests some of these people would survive if VA ECMO is used, and some people may benefit more than others. But there is a lack of good quality

evidence.

VA ECMO is only suitable for a small number of people and is only available in a few hospitals. So, it would be difficult to do randomised controlled trials in

Guidance – VA ECMO for postcardiotomy cardiogenic shock in adults

people with PCS. But other forms of data collection are possible. So, this procedure can be used in the NHS during the evidence generation period.

2 Information about the procedure

- 2.1 Extracorporeal membrane oxygenation (ECMO) can be used to manage postcardiotomy cardiogenic shock immediately after heart surgery, or to help separation from cardiopulmonary bypass.
- 2.2 In venoarterial ECMO, blood is taken from the venous system (usually from the femoral vein or the right atrium) and pumped through an oxygenator, where oxygen and carbon dioxide are exchanged. It is then returned to the arterial system (usually through the femoral or axillary artery or ascending aorta). People are usually given a continuous infusion of an anticoagulant, usually heparin, to prevent blood clotting in the extracorporeal system. For people with poor kidney function, a haemofiltration unit may be added to the circuit.

3 Committee discussion

The condition

3.1 Postcardiotomy refers to the period immediately after open-heart surgery. Postcardiotomy cardiogenic shock (PCS) is a rare but life-threatening situation that happens when the efficiency of the heart as a pump is impaired and is unable to meet the body's tissue demands. This means a person may be unable to be separated from cardiopulmonary bypass after open-heart surgery. Persistent cardiogenic shock cannot be managed with medicines alone.

Current practice

3.2 Treatment for PCS involves pharmacological treatments, including diuretics and inotropic agents, and mechanical circulatory support, including intra-aortic balloon pumps. Without using mechanical

Guidance - VA ECMO for postcardiotomy cardiogenic shock in adults

Issue date: September 2025

Page 5 of 9

circulatory support PCS has a very high risk of death, with mortality reported as high as 76%.

Unmet need

3.3 VA ECMO is used to provide cardiac and respiratory support for people with PCS. Unlike a heart–lung (cardiopulmonary) bypass machine, it tends to be used for days to weeks and not hours during surgery, allowing the heart time to recover. ECMO provides circulatory support and allows time for other treatments to promote recovery, or may be a bridge to a long-term mechanical solution or transplant. It aims to improve patient outcomes.

The evidence

- 3.4 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 12 sources (13 publications), which was discussed by the committee. The evidence included 4 systematic reviews, 3 retrospective registry studies, 1 multicentre retrospective study and 4 single centre retrospective studies. It is presented in the summary of key evidence section in the interventional procedures overview. Other relevant literature is in the appendix of the overview.
- 3.5 The professional experts and the committee considered the key efficacy outcomes to be: restoration of organ function and bridging to recovery, transplant or long-term support.
- 3.6 The professional experts and the committee considered the key safety outcomes to be: bleeding, leg ischaemia, stroke, infection, renal failure and circuit-related complications.
- 3.7 Patient commentary was sought but none was received.

Guidance - VA ECMO for postcardiotomy cardiogenic shock in adults

Issue date: September 2025

Committee comments

- 3.8 Clinical experts advised that some centres provide elective VA ECMO for people who are more likely to have PCS, and it is routinely used in some centres.
- 3.9 Clinical experts advised that VA ECMO can be done either peripherally or centrally. Central VA ECMO is used more commonly after cardiac surgery.
- 3.10 It would be difficult to do randomised controlled trials in people with PCS. So, other types of data collection such as registries could be useful.
- 3.11 The recommendations in this guidance include use of VA ECMO during pregnancy or in the postpartum period.
- 3.12 The committee was told that this procedure could have a better outcome when it is used for post-transplant support because of primary graft dysfunction.
- 3.13 Some people who had VA ECMO have become organ donors and their organs have been transplanted.
- 3.14 The committee was told that starting VA ECMO to manage PCS as early as possible is of high importance for better outcomes.
- 3.15 The committee was told that a high level of nursing expertise and input from a perfusionist are needed to support people on VA ECMO.

Equality considerations

3.16 Not all cardiac surgery centres specialise in using VA ECMO in the UK. So, people in some areas may not have access to this procedure.

Guidance - VA ECMO for postcardiotomy cardiogenic shock in adults

Issue date: September 2025

3.17 Pregnancy and maternity are protected characteristics under the Equality Act (2010). Women, trans men and non-binary people with cardiogenic shock who are pregnant, or who have recently been pregnant, may need to access this intervention.

Committee members and NICE project team 4

This topic was considered by NICE's interventional procedures advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technology to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Chair

Tom Clutton-Brock

Chair, interventional procedures advisory committee

NICE project team

Each evaluation is assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the evaluation), a consultant clinical adviser, a project manager and an associate director.

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Guidance – VA ECMO for postcardiotomy cardiogenic shock in adults

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Issue date: September 2025

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ISBN: [to be added at publication]