NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HealthTech draft guidance

VA ECMO for severe acute heart failure in adults

Heart failure is when the heart cannot properly pump blood around the body to deliver enough oxygen to meet the body's needs. Severe acute heart failure is when life-threatening symptoms develop very quickly.

Venoarterial extracorporeal membrane oxygenation (VA ECMO) is when blood is taken out of the body and put through an artificial lung located outside of the body (extracorporeal). The ECMO machine adds oxygen to the blood (oxygenation), removes carbon dioxide and pumps the blood around the body. This is done over days or weeks. Tubes take blood out of the major veins in the groin, neck, or both, and return it through tubes into a large artery (venoarterial).

VA ECMO aims to do the work of the heart to provide oxygenated blood to the body while the heart recovers 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 effective 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.

Issue date: April 2025

NICE is producing this guidance on VA ECMO for severe acute heart failure in the NHS in England. The interventional procedures advisory committee has considered the evidence and the views of clinical and patient experts.

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 clinical effectiveness 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 severe acute heart failure. 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: 21 May 2025

Second committee meeting: 10 July 2025

1 Recommendations

As a bridge to recovery, heart transplant or implanted LVAD

1.1 Venoarterial extracorporeal membrane oxygenation (VA ECMO) can be used as an option for severe acute heart failure as a bridge to recovery, a heart transplant or an implanted left ventricular assist device (LVAD).

When recovery is unlikely and a heart transplant or implanted LVAD is not suitable

1.2 More research is needed on VA ECMO for severe acute heart failure when recovery is unlikely and a heart transplant or implanted LVAD is not suitable, before it can be used in the NHS.

1.3 This procedure should only be done as part of formal research and an NHS research ethics committee needs to have approved its use.

What research is needed

More research is needed on:

- patient selection including age, comorbidities, and cause of severe acute heart failure
- short- and long-term outcomes.

What this means in practice

As a bridge to recovery, a heart transplant or an implanted LVAD

There is enough evidence on the safety and efficacy of this procedure for clinicians to consider VA ECMO as an option for severe acute heart failure.

Clinicians do not have to offer this procedure and should always discuss the available options before making a decision. You can find out more on our webpage on making decisions about your care.

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.

When recovery is unlikely and a heart transplant or an implanted LVAD is not suitable

There is not enough evidence to know if this procedure is effective when recovery is unlikely and a heart transplant or an implanted LVAD is not suitable. VA ECMO should only be done as part of formal research in this group.

For everyone having the procedure

Auditing of outcomes

Clinicians 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 in the procedure

Patient selection should be done by a multidisciplinary team. The procedure should only be done in centres specialising in managing severe acute heart failure with specific training in this procedure.

Why the committee made these recommendations

VA ECMO is not a treatment for severe acute heart failure. It is a short-term intervention to stabilise a person's condition while they recover or before they have a heart transplant or an implanted LVAD.

The prognosis for severe acute heart failure can depend on its causes, so recovery is more likely in some people. Evidence suggests that VA ECMO improves survival in these people while they recover or before having a heart transplant or an implanted LVAD.

For people with a low chance of recovery who cannot have a heart transplant or an implanted LVAD, clinical trial evidence suggests that there is no benefit from VA ECMO. This may be because of the cause of their severe acute heart failure or because of their comorbidities. For this group, more research is needed on who might benefit and so VA ECMO should only be used in research.

2 Information about the procedure

2.1 Venoarterial extracorporeal membrane oxygenation (VA ECMO) can be offered to adults with severe acute heart failure as a bridge to recovery or having a heart transplant or an implanted left ventricular assist device.

2.2 In VA ECMO, blood is taken from the venous system (usually from the femoral vein or directly from 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 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 Acute heart failure is a complex clinical syndrome of symptoms and signs that happen when the efficiency of the heart as a pump is impaired. It can lead to reduced blood flow to the body and increased filling pressures in the heart. Cardiogenic shock is the most severe form of acute heart failure, with short-term mortality between 30% and 50%. It can be caused by a heart attack, heart failure, inflammation of the heart muscle, drug overdoses and poisoning, and blood clots in the lungs. Severe acute heart failure in pregnancy is relatively uncommon, but rates are increasing, particularly in the postpartum period.

Current practice

3.2 NICE has published recommendations on diagnosing and managing acute heart failure (see NICE's guideline on acute heart failure: diagnosis and management). Acute heart failure includes sudden significant deterioration in people with known cardiac dysfunction or new onset of symptoms in people without previous cardiac dysfunction. Treatment involves medicines, including diuretics and inotropic drugs, and invasive treatments such as:

- electrophysiological intervention such as pacemakers or implantable cardioverter-defibrillators
- revascularisation procedures such as percutaneous coronary intervention, valve replacement or repair, and
- temporary use of intra-aortic balloon pumps or ventricular assist devices.

Most acute heart failure can be managed with conventional treatment. Only a small number of people with severe acute heart failure will need venoarterial extracorporeal membrane oxygenation (VA ECMO).

Unmet need

3.3 VA ECMO is a form of extracorporeal life support. It provides cardiac and respiratory support for people with severe acute heart failure that has not responded to other forms of treatment. VA ECMO is used when people have the potential to recover or as a bridge to having a heart transplant or an implanted left ventricular assist device. Unlike a heart–lung (cardiopulmonary) bypass machine, it tends to be used for days to weeks and not hours during open heart surgery, allowing the heart time to recover. 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 9 sources, which was discussed by the committee. The evidence included 4 systematic reviews, 3 randomised controlled trials, 1 retrospective registry study and 1 single centre retrospective study. 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: survival, 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, kidney failure and circuit-related complications.

3.7 Patient commentary was sought but none was received.

Committee comments

3.8 The committee noted that VA ECMO should only be done in centres specialised in managing severe acute heart failure and providing VA ECMO.

3.9 The committee noted that this is a short-term intervention to stabilise people's conditions and bridge them to further treatment or decisions about their care. Some people will recover, and others will need a heart transplant or long-term mechanical support.

3.10 The committee was told that reducing the time to starting VA ECMO is of high importance for better outcomes.

3.11 The committee was told that people can be moved from other non-specialised centres to have VA ECMO.

3.12 The committee noted the incidence of limb ischaemia but that this has reduced since distal limb perfusion has been in use.

3.13 The committee noted that the recommendations in this guidance include the use of ECMO during pregnancy or in the post-partum period.

Equality considerations

3.14 The committee noted that there are few centres in the UK that specialise in managing severe acute heart failure and using VA ECMO. So, people in more rural areas may not have access to this intervention.

3.15 The prevalence of heart failure slowly increases with age until about 65 years, and then more quickly. Age is a protected characteristic under the Equality Act (2010).

3.16 Acute heart failure in pregnancy is relatively uncommon. Women, trans men and non-binary people who are pregnant and have established chronic conditions such as diabetes or hypertension, or

have congenital or acquired heart disease are at greater risk of heart failure. Pregnancy and maternity are protected characteristics under the Equality Act (2010).

4 Committee members and NICE project team

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.

Jessica Wilcock and Helen Gallo

Technical leads

Alan Ashworth

Consultant clinical adviser

Corrina Purdue

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Associate directors

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