# Extracorporeal membrane oxygenation for severe acute respiratory failure in adults

Interventional procedures guidance
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## Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

This guidance replaces IPG39.

# 1 Recommendations

1.1 Evidence on the safety of extracorporeal membrane oxygenation (ECMO) for severe acute respiratory failure in adults is adequate but shows that there is a risk of serious side effects. Evidence on its efficacy is inadequate to draw firm conclusions: data from the recent CESAR (conventional ventilation or extracorporeal membrane oxygenation for severe adult respiratory failure) trial was difficult to interpret because different management strategies were applied among many different hospitals in the control group and a single centre was used for the ECMO treatment group. Therefore, this procedure should only be used with special arrangements for clinical governance, consent and research.

1.2 Clinicians wanting to do ECMO for severe acute respiratory failure in adults should:

- Inform the clinical governance leads in their trusts.
- Whenever possible, ensure that patients and their carers understand the uncertainty about the procedure's efficacy and its risks and provide them with clear written information. In addition, the use of NICE's information for the public is recommended.

1.3 Extracorporeal membrane oxygenation for severe acute respiratory failure in adults should only be carried out by clinical teams with specific training and expertise in the procedure.

1.4 Clinicians are encouraged to submit data on all adults undergoing ECMO for severe acute respiratory failure to the Extracorporeal Life Support Organization Registry.

1.5 NICE encourages further research into the use of innovative technologies for the management of severe acute respiratory failure, and may review this guidance on publication of further evidence.

# 2 The procedure

## 2.1 Indications and current treatments

2.1.1 Extracorporeal membrane oxygenation (ECMO) is a supportive therapy for adults, including during or soon after pregnancy, with severe acute respiratory failure from a potentially reversible cause. Extracorporeal membrane systems mimic gas exchange in the lungs by eliminating some carbon dioxide from the blood and adding oxygen.

2.1.2 There are many causes of severe acute respiratory failure, including acute respiratory distress syndrome, pneumonia, and chest trauma.

2.1.3 Conventional treatment involves maximum medical support, including mechanical ventilation. Arteriovenous extracorporeal membrane carbon dioxide removal, also known as pumpless extracorporeal lung assist, can also be used to support gas exchange.

## 2.2 Outline of the procedure

2.2.1 Extracorporeal membrane oxygenation for severe acute respiratory failure in adults aims to reduce ventilator-induced lung injuries and improve patient outcomes.

2.2.2 There are 2 main types of ECMO: venovenous ECMO (for respiratory support) and

venoarterial ECMO (for cardiac and mixed cardiac and respiratory support). In venovenous ECMO, desaturated blood is withdrawn from the venae cavae and pumped through an oxygenator, where gas exchange of oxygen and carbon dioxide takes place. The oxygenated blood is then returned to the venous system. In venoarterial ECMO, blood is withdrawn from the venous system and returned to the arterial system. In both systems, patients are given a continuous infusion of an anticoagulant, usually heparin, to prevent blood clotting in the external system.

## 2.3 Efficacy

Sections 2.3 and 2.4 on efficacy and safety describe efficacy and safety outcomes from the published literature that the committee considered as part of the evidence about this procedure. More detailed information on the evidence is presented in the overview.

2.3.1 A randomised controlled trial (RCT) of 180 patients treated by ECMO or conventional management reported death or severe disability in 37% (33 out of 90) and 53% (46 out of 87; there was no information about 3 patients) of patients respectively at 6-month follow up (relative risk [RR] 0.69, 95% confidence interval [CI] 0.05 to 0.97).

2.3.2 A non-randomised comparative study of 245 patients treated by ECMO or conventional treatment reported survival to hospital discharge in 55% (34 out of 62) and 61% (absolute figures not stated) of patients respectively (p=not significant). A non-randomised comparative study of 150 patients treated by ECMO or conventional treatment reported survival rates of 53% (17 out of 32) and 71% (84 out of 118) respectively (p=0.06). All patients in these studies treated by ECMO had more severe disease than controls.

2.3.3 The RCT of 180 patients treated by ECMO or conventional management reported similar levels of overall health status scores in both groups at 6 months (67.9 versus 65.9; measured on a visual analogue scale from 0 to 100, where a higher score indicates a better health status).

2.3.4 The specialist advisers listed key efficacy outcomes as successful weaning from ECMO, successful weaning from ventilation, improved survival and quality of life.

## 2.4 Safety

2.4.1 The non-randomised comparative study of 245 patients and the case series of 255 patients both reported that 5% of patients (3 out of 62 in the comparative study, no actual figures were given for the case series) developed disseminated intravascular coagulation.

2.4.2 Vessel perforation during cannulation contributed to the death of 1 patient out of 68 treated by ECMO in the RCT of 180 patients.

2.4.3 Difficulties or injuries during cannulation were reported in 8% (5 out of 62) of patients in the non-randomised comparative study of 245 patients; 1 patient required surgical intervention to repair an injury to the carotid artery.

2.4.4 The non-randomised comparative study of 245 patients and case series of 1,473 and 255 patients reported rupture of the ECMO tubing system in 5% (3 out of 62), 4% (64 out of 1,473) and 3% (actual numbers not stated) of patients respectively. Of the patients in the non-randomised comparative study, brain death was diagnosed in 1 patient after resuscitation and reinstitution of ECMO.

2.4.5 The specialist advisers listed anecdotal adverse events as air embolism, thromboembolic events, sepsis, multi-organ failure and mechanical failure.

## 2.5 Other comments

2.5.1 The committee recognised the importance of the CESAR trial and the reasons for its pragmatic design.

# 3 Further information

3.1 Information about provision is available in NHS England's service specification for extra corporeal membrane oxygenation for respiratory failure in adults.

## Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

## Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.