

Extracorporeal membrane oxygenation (ECMO) in postneonatal children

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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 <u>Yellow Card Scheme</u>.

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 <u>assess and reduce the environmental</u> <u>impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

- 1.1 Current evidence on the safety and efficacy of extracorporeal membrane oxygenation in postneonatal children appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.
- 1.2 All children undergoing this treatment, including those treated after cardiopulmonary bypass, should be entered onto the international registry of the <u>Extracorporeal Life Support Organization</u> (ELSO).

2 The procedure

2.1 Indications

- 2.1.1 Extracorporeal membrane oxygenation (ECMO) is used to treat respiratory or cardiac failure that is unresponsive to all other measures, but is considered to have a reversible cause. ECMO may be used following heart surgery in postneonatal children to ease the transition from cardiopulmonary bypass. Postneonatal children are at least one month old.
- 2.1.2 Most children treated with ECMO are very ill and at risk of death. The causes of respiratory and cardiac failure in children include: pneumonia; septic shock; congenital heart disease; cardiomyopathy; severe burns; and pulmonary haemorrhage.

2.1.3 Standard treatment is maximal intensive care support without ECMO.

2.2 Outline of the procedure

2.2.1 ECMO is a temporary life support technique. It involves connecting the patient's internal circulation to an external blood pump and artificial lung. A catheter placed in the right side of the heart carries blood to a pump, then to a membrane oxygenator (artificial lung), where gas exchange of oxygen and carbon dioxide takes place. The blood then passes through tubing back into either the venous or arterial circulation. Patients are given an anticoagulant to prevent blood clotting in the external system.

2.3 Efficacy

- 2.3.1 Most of the evidence reviewed comprised case series from the ELSO database, and these ranged in size from 67 to 763 patients. Survival rates ranged from 40% (27/67 patients) to 71% (91/128 patients). The largest case series of 763 patients reported a 57% survival rate. For more details, refer to the 'Sources of evidence' section.
- 2.3.2 The Specialist Advisors considered that the efficacy of ECMO in providing cardiorespiratory support in postneonatal children is proven. They considered that survival in this group of patients is reasonably well known from the worldwide ELSO database.

2.4 Safety

2.4.1 From the studies, the most common complications included bleeding (with an incidence between 40% [27/67] and 58% [137/237]) and renal failure (the largest case series reported this at 45% [343/763]). Other, less frequent complications included seizures and haemolysis. For more details, refer to the 'Sources of evidence' section.

2.4.2 The Specialist Advisors considered that the incidence of complications associated with ECMO was low. They listed infection, bleeding, neurological damage and technical problems with the ECMO circuit as potential complications. However, they considered that the procedure was sufficiently well-established in the centres in which it was used and was delivered by trained specialists in a manner designed to minimise risks.

2.5 Other comments

2.5.1 The Health Technology Assessment Programme's CESAR trial (Conventional Ventilation or Extracorporeal Membrane Oxygenation for Severe Adult Respiratory Failure) will provide additional evidence about the use of the procedure in adults.

3 Further information

Sources of evidence

The evidence considered by the interventional procedures advisory committee is described in the <u>overview for this guidance</u>.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.