

2013/14 NHS Standard Contract

**EXTRA CORPOREAL MEMBRANE OXYGENATION SERVICE FOR NEONATES,
INFANTS AND CHILDREN WITH RESPIRATORY FAILURE**
Section B Part 1 – service specifications

Service Specification No.	E07/S(HSS)/a
Service	Extra corporeal membrane oxygenation service for neonates, infants and children with respiratory failure
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Respiratory extra corporeal membrane oxygenation (ECMO) support is indicated for acute, severe but reversible respiratory failure when the risk of dying from the primary disease despite optimal conventional treatment is high. The duration of ECMO support is related to the underlying disease process. In general terms, it is a prolonged but temporary support (<30 days) of the lungs and sometimes the heart.

The service allows babies and children with severe respiratory distress from a variety of causes and for whom mechanical ventilation is insufficient, to have the function of their lungs (and also heart if needed) supported with a mechanical pump and artificial lung (ECMO). The causes include infection, meconium aspiration, diaphragmatic hernia and occasionally structural problems with lungs or airway. ECMO provides support for gas exchange (oxygenation, and removal of carbon dioxide) and the circulation, allowing time for intrinsic healing of damaged organs while minimising iatrogenic injury. The prerequisite for successful ECMO support is that the underlying condition is reversible.

1.2 Evidence

Despite a number of clinical trials of ECMO in the USA in the 1980s, there remained some doubt about its safety and efficacy. The UK collaborative randomised controlled trial of neonatal ECMO was done between 1993 and 1995. The trial results that ECMO reduced the risk of death or severe disability in this patient population. ECMO data and outcomes are reported internally and externally to NHS England

commissioners and the international Extracorporeal Life Support Organisation (ELSO) registry.

2. Scope

2.1 Aims and objectives of service

ECMO is an invasive treatment of short duration that allows babies and children to be kept alive to enable intrinsic healing or the continuation of their current treatment. The objective of the service is to enhance the survival for patients with severe conditions who would otherwise be unlikely to survive. The success of the service will be determined by the number of children who survive who would otherwise have very little chance of surviving. Outcomes will be measured against the benchmark of the ELSO database and the outcomes in other institutions.

2.2 Service description/care pathway

Referral Patients are usually referred from external hospitals - it is very rare for them to be internal referrals. External patients are referred by their local consultant who telephones the provider directly. Occasionally a referral comes via one of the other ECMO centres. The provider and referrer discuss each referral and agree the best course of action. This can range from advice about treatment, to making the arrangements for the patient to be admitted to a national ECMO centre.

Once it has been established that the patient needs to be assessed for respiratory ECMO, the provider will take responsibility for ensuring smooth patient transfer. This may include arranging transport to another ECMO provider within the UK or internationally.

For all patients requiring ECMO assessment, the appropriate timing for referral and transport remains uncertain. In the neonatal patient group, there are a number of therapies available when escalation of treatment is required, e.g. high frequency ventilation, surfactant or inhaled nitric oxide. The use of these treatments may delay referral. However, respiratory ECMO is recognised as a rescue modality to support a variety of reversible cardio-respiratory failures in neonates and children.

Support is given to referring clinicians through advice on treatment of those patients not suitable for respiratory ECMO support.

Retrieval

For cases in which local transport arrangements are not suitable, NHS England commissions specialist road and air retrieval, including the use of mobile respiratory ECMO where appropriate.

Assessment

All patients up to the aged of 18 needing assessment for ECMO due to respiratory failure are admitted to the cardiac intensive care unit where a consultant intensivist

assesses their needs. During this period a cranial ultrasound is performed to rule out intracranial haemorrhage and an echocardiogram (ECHO) to confirm the patient has a structurally normal heart.

Patients assessed as needing respiratory ECMO support are then cannulated for ECMO and remain on the cardiac intensive care unit.

Appropriate conventional management should be commenced if the respiratory assessment deems that ECMO is not required.

Information is given to the parents about ECMO support and the associated risks related to ECMO, consent is obtained. Usually this means overall risk of death is about 25% with a risk of intra-cerebral haemorrhage or other bleed of about 10%.

Interventions

The main intervention for respiratory ECMO support is surgical insertion of the ECMO cannulae and establishment of ECMO support. Other interventions that may be required in the ECMO patient are the insertion of venous access, or the insertion of chest tubes for chest drainage systems.

Once the patient is on ECMO, their recovery pathway is determined by reference to a set of predefined recovery pathways for each condition. This sets out the multidisciplinary care plan for the duration of their stay including the tests, support interventions etc to be performed. The referring hospital is informed of the expected duration of ECMO treatment and of any changes to this during the patient's stay.

There are agreed clinical pathways for the use of respiratory ECMO with neonates, children and patients with congenital diaphragmatic hernia.

Removal of ECMO support

Patient care is managed through anticipated pathways of recovery. Weaning from respiratory ECMO support is assessed by:

- an increase in lung compliance
- improvement of chest X ray
- visible chest movement on 'resting' ventilation settings
- decreased dependence on membrane lung.

With this information a multidisciplinary decision is made to 'trial off ECMO support'. During this trial, the patient is removed from ECMO support over approximately one hour and a cardio respiratory assessment is made to determine whether to remove the ECMO cannulae or resume support.

Discharge

This service specification does not include repatriation transport. Once the patient is removed from ECMO and no longer requires treatment they are discharged from the care pathway covered by this specification. The patient may be transported back to their referring hospital, or continue with further treatment or surgery within the provider hospital, as agreed with the appropriate commissioner.

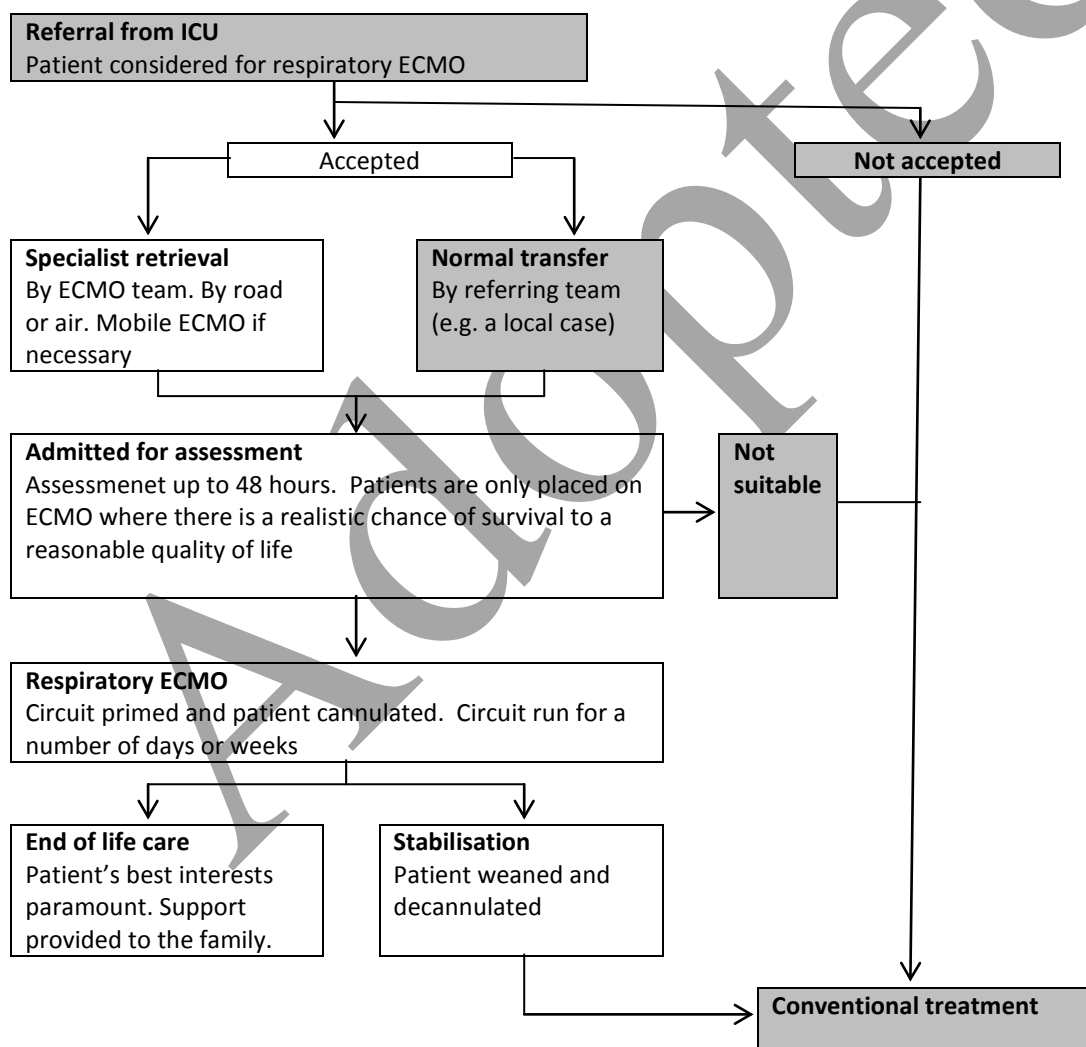
Follow up

Long-term follow up of children who have received ECMO support will be carried out by a paediatrician in the local referring hospital.

Patient and Family Support

Counselling of bereaved families is offered 6 weeks after death of child to review care and provide parents with outstanding results e.g. from post mortem examination. Providers are expected to support families in accessing bereavement and counselling services if required.

Pathway for neonate and child respiratory ECMO



2.3 Population covered

NHS England commissions the service for the population of England. At the moment,

NHS England contract includes provision for the service to treat eligible overseas patients under S2* referral arrangements. Providers are reimbursed for appropriately referred and recorded activity as part of NHS England contract.

*Under EU regulations, patients can be referred for state funded treatment to another European Economic Area (EEA) member state or Switzerland, under the form S2 (for EU member states) or the form E112 (for Iceland, Norway, Liechtenstein and Switzerland)

Trusts performing procedures on EU-based patients outside of S2 arrangements will need to continue to make the financial arrangements directly with the governments involved, separately from their contract with the NHS England.

With regard to S2, the mechanism for recovery of costs has been via the Department for Work and Pensions Overseas Healthcare Team. They are responsible for agreeing reconciliation and recovery of costs with European administrations. These arrangements were implemented in October 2009, though a similar process existed previously. The financial flows are therefore back into the Treasury rather than back to trusts.

2.4 Any acceptance and exclusion criteria

2.4.1 Referral criteria, sources and routes

All providers use the nationally agreed ECMO referral criteria (for more information, please refer to the service standards):

- oxygenation index (OI) >40
- weight > 2kgs
- reversible lung disease
- no lethal congenital anomalies
- no irreversible central nervous system injury
- no major immunodeficiency
- anticoagulation is not contraindicated.

Variations to these criteria may be made on clinical assessment of the individual patient.

The technical success of neonatal ECMO led to the increased use of ECMO in the paediatric population. The paediatric age group is more heterogeneous. Indications for paediatric ECMO include:

- inadequate oxygenation despite appropriate ventilation
- air leak syndrome
- older children OI >25 or Acute deterioration
- large airway disease / disruption making ventilation impossible
- refractory septic shock
- the need for high pressure ventilation in the face of a persistent air leak.

2.4.2 Response time & detail and prioritisation

Initial contact and communication with the referring hospital is made usually within 15 minutes. If advice is sought and other treatment modalities utilised, the process can

take a number of hours and require a number of contacts. If a decision is made to accept the admission and support the child on respiratory ECMO then a referral is made and a transport team is mobilised.

2.4.3 Exclusion criteria

Children are only placed on ECMO where there is a realistic chance of their survival. Where the chances of survival are unclear, such as for patients who have been given a bone marrow transplant, the ECMO physician will make decisions on clinical management using the all sources of information available.

The service is provided for children aged less than 18 years of age.

2.5 Interdependencies with other services

Referrals are from neonatal and paediatric intensive care units (PICU and NICU). All neonatal and paediatric intensive care units are key stakeholders in the national ECMO service.

3. Applicable Service Standards

3.1 Applicable national standards e.g. NICE, Royal College

The providers of the national ECMO service must ensure they are fully integrated into their trust's corporate and clinical governance arrangements and must comply fully with Clinical Negligence Scheme for Trusts (CNST) and Care Quality Commission (CQC) requirements in terms of quality and governance.

Each centre will ensure that there are:

- regular meetings with patient representatives
- all practitioners will participate in continuous professional development and networking
- patient outcome data is recorded and audited across the service.

Clinical teams are expected to participate actively in clinical networks to improve the national respiratory ECMO service.

The ECMO service has an agreed service specification and is supported by detailed clinical practice guidelines.

4. Key Service Outcomes

<i>Quality Performance Indicator examples</i>	<i>Threshold</i>	<i>Method of measurement</i>	<i>Consequence of breach</i>	<i>Report Due</i>
Success of ECMO cannulation	ESLO thresholds	Critical incidence reporting	Review & action plan	By exception
Survival Rates	ELSO thresholds	ELSO reporting included in annual report	Review & action plan	Annual report (September of contract year)
Survival to discharge	Significant variation from the national average or, in services with one of two national centres significant variation from the outcomes achieved in the previous three years	Annual report (September of contract year) with data from previous financial year April to March	Performance notice as set out in Clause 32.4 Review & action plan	Annual report (September of contract year)

5. Location of Provider Premises

Great Ormond Street Hospital for Children NHS Foundation Trust
 The Newcastle upon Tyne Hospitals NHS Foundation Trust
 University Hospitals of Leicester NHS Trust