D16/S(HSS)/a

2013/14 NHS STANDARD CONTRACT
FOR EXTRA CORPOREAL MEMBRANE OXYGENATION SERVICE FOR ADULTS WITH RESPIRATORY FAILURE

PARTICULARS, SCHEDULE 2 – THE SERVICES, A – SERVICE SPECIFICATION

Service Specification No.	D16/S(HSS)/a
Service	Extra corporeal membrane oxygenation service for adults with respiratory failure
Commissioner Lead	
Provider Lead	
Period	12 months
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

Context

Extracorporeal life support is used to replace the function of failing lungs due to acute lung injury or acute respiratory distress syndrome (ARDS). These are life threatening conditions initiated by a broad range of clinical diagnoses (including infection and trauma) but characterised by acute lung inflammation causing pulmonary oedema, refractory hypoxia and reduced lung compliance.

Evidence Base

The first ECMO trial was conducted in the USA in the 1970's and showed no survival benefit. There was a further trial in the 1980s using a modified form of ECMO called ECCOR (Extra Corporeal Carbon Dioxide Removal). This also failed to show benefit. The most recent evidence, which did show benefit, includes a case control study from Leicester reported in 1997, the Conventional Ventilation or ECMO for Severe Adult Respiratory Failure (CESAR) Trial (2001-2006) reported in 2009 and conducted in the UK and the results of a case comparison study carried out during the swine flu pandemic in 2009/2010 (in press).

The CESAR trial recommended transferring adult patients with potentially reversible

severe respiratory failure whose Murray score exceeds 3.0 or who have a pH of less than 7.20 on optimal conventional management, to a centre with an ECMO-based management protocol to significantly improve survival without severe disability.

At the end of December 2010, the Department of Health commissioned an expert review of adult hypoxia published the best practice guidance: *The Management of Severe Refractory Hypoxia in Critical Care in the UK in 2010*. The recommendations proposed the development of a tiered model of advanced respiratory care. During a period of high demand (December 2010 and January 2011), the National Specialised Commissioning Team (NSCT) worked closely with the provider centres and critical care network leads to develop a system of triaging referrals from local hospitals through the tertiary high volume intensive care units in that region. The role of the identified tertiary intensive care units (ICU) was to provide advice on management of the case and, where appropriate, ensure onward referral to the national adult respiratory ECMO service.

References:

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2. Scope

2.1 Aims and objectives of service

Aim

To commission an adult respiratory ECMO service to meet the needs of critically ill patients with potentially reversible severe respiratory failure in whom ECMO support is clinically appropriate and who fulfil the eligibility criteria for the service.

Respiratory ECMO provision will be within a tertiary level ICU which is able to provide expert advice on the diagnosis and management of potentially reversible severe respiratory failure and is part of the wider critical care network.

It is expected that the service will be delivered through a number of providers to ensure patients have equity of access and receive parity of service. Except in exceptional circumstances, the ECMO centre should retrieve all patients who are accepted for treatment/consideration of ECMO.

Objectives

Each provider will:

- provide a high quality and comprehensive service for all eligible referred patients aged 16 years and over
- meet the national standards for respiratory ECMO, as a minimum, and participate in their on-going development
- have the expertise to manage patients with potentially reversible severe respiratory failure through the use of the most up-to-date clinical practice
- be able to provide ECMO in cases which meet the eligibility criteria with each centre able to meet minimum volume standards
- manage services during both anticipated seasonal pressures or unanticipated surges in demand
- rapidly admit, assess and treat all patients (aged 16 years and over) who are clinically eligible
- provide ECMO within a tertiary level intensive care unit which has expertise in the specialist management of patients with acute respiratory failure including and the ability to support patients with multi-organ failure
- when necessary, collaborate with other national providers of adult ECMO to minimise potential delays in patients accessing respiratory ECMO care
- have the capacity to safely retrieve patients from referring hospitals to the receiving ECMO centre
- make arrangements for the safe repatriation of patients from the ECMO centre to an appropriate hospital near their home
- be able to provide safe mobile ECMO for patients who are clinically eligible, within 12 months of commencing the service

- collaborate and participate with all other national providers of adult ECMO to provide a national “surge” in capacity if required
- collaborate and participate with all other national providers of adult ECMO in joint audit and service development
- register with the Extracorporeal Life Support Organisation (ELSO), submit data according to agreed ELSO deadlines, and achieve survival rates equivalent to the best in the world.

2.2 Service description/care pathway

Service description

The service is commissioned to provide extracorporeal life support to patients with potentially reversible severe respiratory failure in an adult population (aged 16 years or over). However, there may be rare exceptions when a patient aged between 16 and 18 is more appropriately admitted under the paediatric respiratory ECMO service.

Extracorporeal life support is used to replace the function of failing lungs due to acute lung injury or acute respiratory distress syndrome (ARDS). These are life threatening conditions initiated by a broad range of clinical diagnoses (including infection and trauma) but characterised by acute lung inflammation causing pulmonary oedema, refractory hypoxia and reduced lung compliance.

ECMO is a form of support rather than a treatment and its aim is to maintain physiological homeostasis to allow the lung injury or infection to recover. This usually requires a support time between five and fourteen days. On occasions, it may be necessary to extend ECMO support beyond fourteen days.

Venous-venous ECMO is preferred for adult respiratory failure when cardiac function is adequate or mildly depressed.

Patients on ECMO require anticoagulation with heparin due to use of the extracorporeal circuit. The main contraindications for ECMO support relate to the possibility of bleeding so are usually contraindicated in patients with a recent intracranial bleed, trauma (particularly with a head injury) or recent surgery or bleeding from the GI tract. Weight over 125 kg can be associated with technical difficulty in cannulation, and the risk of not being able to achieve an adequate blood flow based on patient size.

Care Pathways

The adult respiratory ECMO service care pathway encompasses:

- referral and acceptance of patients who fulfil eligibility criteria for service (**see section 3.1**)
- specialist retrieval
- assessment (up to a maximum of 48 hours)
- treatment - by provision of extracorporeal life support using a standard

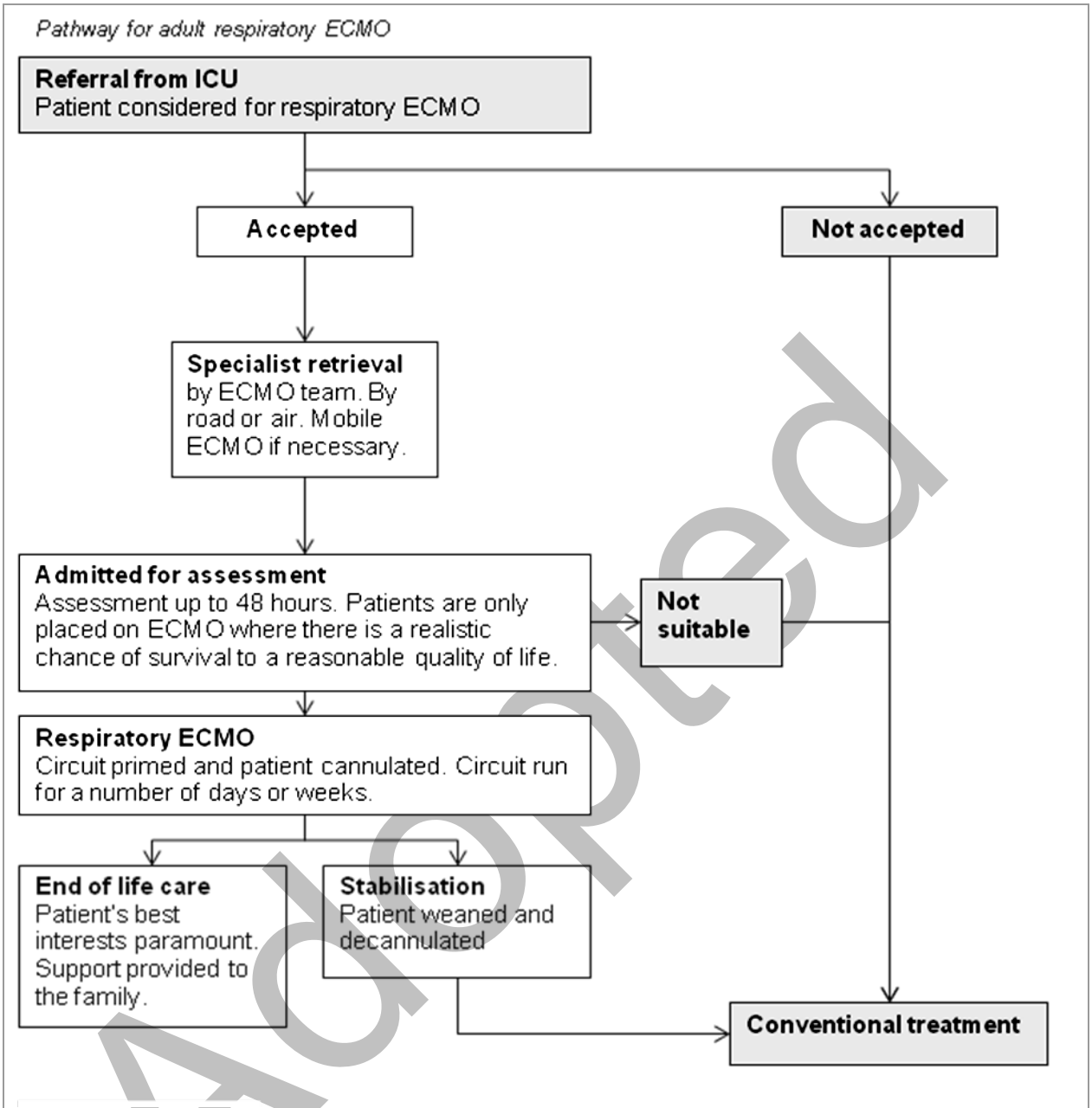
protocolised pathway of care

- post treatment support (post decannulation up to a maximum of 48 hours)
- end of life care.

Patients discharged from the specialist ECMO service following the period of post ECMO support should be transferred back to the critical care team.

Centres will be expected to:

- anticipate, plan for and manage seasonal variation
- respond on a national basis to unanticipated surges in demand, over and above the seasonal demands. This may impact on the trust's capacity to provide elective services.



Referral processes and sources

2.2.1 Patient referral

Patient referral

Referrals to the service should only be made by adult intensive care units for patients who are critically ill and already receiving lung protective mechanical ventilation

Providers will accept patients referred to the service who:

- have potentially reversible severe respiratory failure
- have failed optimal conventional intensive care management
- meet the agreed objective eligibility criteria for the respiratory ECMO service; these will be based on the CESAR criteria.

To fulfil the CESAR eligibility criteria the patient will have severe but potentially reversible severe respiratory failure, defined as a Murray score ≥ 3.0, or uncompensated hypercapnoea with a pH < 7.20 despite optimal conventional treatment. Reversibility will be based on expert clinical opinion.

The Murray score uses four variables to assess the acuity of lung injury:

- oxygenation
- radiographic findings Chest X-ray changes
- level of positive end expiratory pressure (PEEP) used in mechanical ventilation
- lung compliance.

It may be appropriate to discuss patients when the Murray score is ≥ 2.5 as if the patient continues to deteriorate the referral process can be expedited.

Exclusion criteria

Patients will not usually be eligible if they have:

- been on high pressure (peak inspiratory pressure > 30 cmH2O) and/or high FiO2 (> 0.8) ventilation for more than 7 days (168 hours)
- signs of intracranial bleeding
- other contraindication to limited heparinisation
- any contraindication to continuation of active treatment.

Specialist retrieval

It is the responsibility of ECMO centres to retrieve patients where a direct referral has been made for consideration of ECMO support. This will require that each centre has:

- a dedicated transport team which can transport patients by road or by air
- the ability to undertake mobile ECMO for the group of critically ill patients whose respiratory function is too poor to transfer safely unless established on ECMO at the referring hospital.

Patient pre-ECMO management

Advanced ventilatory support is commissioned up to a maximum of 48 hours, for all eligible critically ill patients accepted by the service for clinical assessment for respiratory ECMO support. Some patients may be managed through maximising their conventional care by the use of advanced ventilatory support techniques and will not require ECMO support. Approximately 20% of patients come into this category.

Conventional intensive care is <u>not</u> commissioned after the initial 48 hour period of

assessment for respiratory ECMO support.

Patient ECMO support

ECMO support is commissioned for patients with potentially reversible severe respiratory failure who are eligible to access the service. It is expected that venous-venous ECMO will be undertaken when supporting patients with severe respiratory failure unless there is a clinical indication for venoarterial ECMO.
A patient is weaned from ECMO support once they demonstrate clinical improvement in respiratory parameters including measures of lung compliance, radiological changes and improvement in blood gas exchange.

If lung function remains poor, or further deteriorates, after a prolonged period of ECMO support (greater than 14 days) it is expected that the centre will discuss the clinical management of the case with one of the other ECMO providers.

Post treatment support

Once a patient has been weaned from ECMO support, decannulated and is clinically stable it is expected that they will be discharged from the ECMO service to the care of the intensive care team.

Post-ECMO support is commissioned up to a maximum of 48 hours following decannulation. Conventional critical care is funded by the patient's Clinical Commissioning Group (CCG).

Transport to repatriate patients back to their referring hospital is not within the scope of this service.

End of life care

There are some patients, who will fail to improve despite ECMO support and on these occasions it may not be clinically appropriate to continue ECMO support. In such cases the multi-disciplinary team should meet to discuss treatment options; family members should be included. The patient's best interests are paramount in these situations.

End of life care is included within the scope of the service and it is expected that providers will follow best practice, for example use of the Liverpool Care Pathway.

Providers should share examples of good practice.

Patient information and family support

Providers will ensure that information is available for relatives at all stages of the care pathway. This will include information on:

- ***Retrieval***: relatives should be informed about the retrieval process with

particular reference to the associated risks. Assent must be obtained from the family obtained.

- ***Assessment, treatment: and post-ECMO:*** regular contact and discussion will be maintained with families, either directly or on the telephone as indicated. The services of a chaplain or a psychologist will be available.
- ***End of life care***: bereavement and counselling services should be available and will be offered to all families.

Follow-up

Patients are not routinely followed-up. However, a patient may be seen as required at the request of the general practitioner or referring hospital. All reasonable requests will be accommodated.

2.2.4 Equity of access to services

NHS England is committed to ensuring equality of access and non-discrimination, irrespective of age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex (gender) or sexual orientation.

2.3 Population covered

The service outlined in this specification is for individuals ordinarily resident in England*; or who are the commissioning responsibility of the NHS in England (as defined in *Who Pays?: Establishing the Responsible Commissioner* and other Department of Health guidance relating to individuals entitled to NHS care).

Additionally the UK has a reciprocal arrangement for international referrals with European countries, most notably Sweden.

2.4 Any acceptance and exclusion criteria

Acceptance criteria

Referrals to the service should only be made by adult intensive care units for patients who are critically ill and already receiving lung protective mechanical ventilation

Providers will accept patients referred to the service who:

- have potentially reversible severe respiratory failure
- have failed optimal conventional intensive care management
- meet the agreed objective eligibility criteria for the respiratory ECMO service; these will be based on the CESAR criteria.

To fulfil the CESAR eligibility criteria the patient will have severe but potentially reversible severe respiratory failure, defined as a Murray score **≥ 3.0,** or

uncompensated hypercapnoea with a pH < 7.20 despite optimal conventional treatment. Reversibility will be based on expert clinical opinion.

The Murray score uses four variables to assess the acuity of lung injury:

- oxygenation
- radiographic findings Chest X-ray changes
- level of positive end expiratory pressure (PEEP) used in mechanical ventilation
- lung compliance.

It may be appropriate to discuss patients when the Murray score is ≥ 2.5 as if the patient continues to deteriorate the referral process can be expedited

Exclusion criteria

- conventional care (including critical care) once a patient is discharged from the adult respiratory ECMO care pathway. This is funded by the patient's Clinical Commissioning Group
- repatriation transport back to referring centre.

2.5 Interdependencies with other services

Providers of respiratory ECMO must be an active member of the Extracorporeal Life Support Organization (ELSO), and provide international benchmarked data to commissioners.

A multi-centre forum exists to facilitate best practice development between respiratory ECMO providers, and includes international members from the Karolinska Institute in Sweden.

Interdependent services

Provision of ECMO should be within tertiary intensive care units which has expertise in the specialist management of severe respiratory failure and is part of the local critical care network. There must be co-location of cardiothoracic surgery.

It is expected that providers are always able to maintain an adult respiratory ECMO capability, despite competing pressures from other services.

3. Applicable Service Standards

Each centre must comply with the national standards for Extra Corporeal Membrane Oxygenation (ECMO) for patients over 16 years of age with severe potentially

reversible respiratory failure. These are attached as an Appendix to the specification.

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

To be agreed in 2013/14

4. Key Service Outcomes

1.1. Measures

Quality Performance Indicator	*Threshold*	*Method of measurement*	*Consequence of breach*	*Report Du*
Mortality	40%	monthly monitoring report	Review and action plan	Monthly
Success of cannulation	ELSO threshold	Critical incident reporting	Review and action plan	6 monthly
Survival rate	ELSO threshold	ELSO reporting	Review and action plan	6 monthly
Survival to discharge	Significant variation from the national average or, in services with one or 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 and action plan	Annual re (Septembe contract ye

The Extracorporeal Life Support Organisation (ELSO) provides the international summary of outcome data for different patient groups and also produces a centre specific report with outcome data for all centres registered with the organisation. The data provided in the annual report includes outcome data but also information on patient and circuit complications. This enables benchmarking of centres. Providers will need to submit a copy of the ELSO annual report to commissioners.

Serious incident reporting is managed in line with each provider's clinical governance process. Any changes in practice should be highlighted in the annual multi-centre meetings to help disseminate good practice.

A microbiology team is expected to be involved in the day to day prescription and monitoring of infection control in patients. Specific notifiable diseases should be reported to Local Authority Proper Officers under the Health Protection (Notification) Regulations 2010:

The ICU will submit data to the Intensive Care National Audit & Research Centre (ICNARC) Case Mix Programme and meet the programme's quality outcome measures

Providers will comply with legislation and statutory guidance to safeguard children and young people (Children Act 1989 and 2004, Working Together to Safeguard Children, 2006

5. Location of Provider Premises

Guy's and St Thomas' NHS Foundation Trust
Papworth Hospital NHS Foundation Trust (Cambridge)
Royal Brompton and Harefield NHS Foundation Trust
University Hospital of South Manchester NHS Foundation Trust
University Hospitals of Leicester NHS Trust