SCHEDULE 2 – THE SERVICES

A. Service Specifications

Service Specification No:	170110S
Service	Extra Corporeal Membrane Oxygenation (ECMO) for Respiratory Failure in adults
Commissioner Lead	
Provider Lead	*For local completion*

1. Scope

1.1 Prescribed Specialised Service

This service specification covers the provision of extra corporeal membrane oxygenation in adults as identified in section 51 of the NHS England Prescribed Specialised Services Manual (The Manual).

1.2 Description

Extra corporeal membrane oxygenation (ECMO) services for adults with severe potentially reversible respiratory failure include services provided by highly specialist adult ECMO centres, including outreach when delivered as part of a provider network.

1.3 How the Service is Differentiated from Services Falling within the Responsibilities of Other Commissioners

NHS England will commission this highly specialised service from designated specialised centres who are already commissioned to provide tertiary adult intensive care services.

Patients requiring treatment by this service are regarded as highly complex requiring highly specialist input.

This service is commissioned by NHS England because the number of individuals requiring the service is small, the cost of providing the service is very high and because of the specialist interventions and specialised staff trained required to provide this service.

Clinical Commissioning Groups (CCGs) do not commission any elements of this service.

2. Care Pathway and Clinical Dependencies

2.1 Care Pathway

ECMO is a form of life support used for patients with severe respiratory failure with a potentially reversible cause. ECMO can be used to support patients with any form of potentially reversible severe respiratory failure. Its aim is to support physiological homeostasis whilst the lung injury recovers. It requires a highly trained multidisciplinary team (MDT) to manage patients.

The adult respiratory ECMO service care pathway encompasses:

- provision of advice to referring clinicians
- acceptance of patients referred to the service who fulfil the eligibility criteria for entry to the service
- specialist retrieval, including mobile ECMO
- assessment (up to a maximum of 48 hours)
- treatment: provision of extracorporeal life support for respiratory failure
- post treatment support (post decannulation up to a maximum of 48 hours)
- follow-up care for patient and their families
- end of life care.

Patients discharged from the specialist ECMO service (following the period of post ECMO support) should be transferred back to the referring critical care team or an appropriately designated adult critical care unit close to the patient's home. If required, support may be sought from the appropriate Critical Care Operational Delivery Network (ODN). Repatriation should occur within 48 hours of the decision to repatriate.

ECMO centres will be expected to:

- anticipate, plan for and manage seasonal variation, and
- respond on a national basis to unanticipated surges in demand, over and above the seasonal demands.

The service is delivered through designated providers to ensure patients have equity of access and receive parity of service. Except in exceptional circumstances, the ECMO service should retrieve all patients who are accepted for consideration of ECMO. Centres must be able to provide safe retrieval, including mobile ECMO, 24 hours a day, 365 days a year.

Patient Referral

Referrals to the service should be made by adult intensive care units for patients who are critically ill with severe respiratory failure refractory to conventional ventilation strategies.

ECMO centres will provide advice to referring clinicians on the management of patients with severe acute respiratory failure.

ECMO centres will accept patients referred to the service who:

- have potentially reversible severe respiratory failure
- have failed optimal conventional intensive care management

- meet the eligibility criteria for the respiratory ECMO service

Eligibility Criteria

ECMO is a bridge to recovery and reversibility of the presenting condition is a key criterion for inclusion in the service. Reversibility will be based on expert clinical opinion.

Bridging to lung transplant is not part of this service specification.

Inclusion Criteria:

- patients with demonstrable severe respiratory failure from a non-cardiac cause (i.e. Murray Lung Injury score 3.0 or above, or uncompensated hypercapnia with a pH < 7.20 despite optimal conventional treatment);
- patients for whom ongoing positive pressure ventilation is not appropriate (e.g. significant tracheal injury).

Exclusion Criteria:

- patients with contraindication to continuation of active treatment;
- patients with significant co-morbidity likely to lead to dependency to ECMO support (e.g. profound muscle weakness, significant irreversible pulmonary fibrosis due to either underlying disease or duration of mechanical ventilation);
- patients with significant life limiting co-morbidity (e.g. advanced malignancy, severely immunocompromised patients).

2.2 Interdependence with Other Services

Adult respiratory ECMO centres must:

- be located within tertiary intensive care units with expertise in the specialist management of severe respiratory failure;
- be part of a local critical care ODN;
- be co-located with cardiothoracic surgery;
- work collaboratively as part of a national network;
- adhere to the NHS England “Management of surge and escalation in critical care services: standard operating procedure for adult respiratory extra corporeal membrane oxygenation”;
- support NHS England Emergency Preparedness, Resilience and Response (EPRR) planning in relation to any incident, event or outbreak of disease that may result in the need for treatment by a specialist adult respiratory ECMO Centre.

3. Population Covered and Population Needs

3.1 Population Covered by this Specification

This specification is for patients aged 16 years and over with respiratory failure refractory to conventional therapy.

By exception, and following collaboration and agreement with a designated paediatric respiratory ECMO centre, it may be clinically appropriate to provide treatment to a younger patient, where it is agreed that their clinical condition or presenting co-morbidities may be more suited to management within an adult service.

This service specification relates to the population defined as the commissioning responsibility of NHS England as set out in *"Who Pays? Determining responsibility for payments to providers*" (2013) guidance https://www.england.nhs.uk/wp-content/uploads/2014/05/who-pays.pdf (or subsequent published updates).

Commissioning arrangements for the devolved nations in relation to this service are as set out in "*UK-wide Commissioning Arrangements of Highly Specialised Services*" https://www.england.nhs.uk/publication/nhs-providers-of-highly-specialised-services/

3.2 Population Needs

This service will provide ECMO as a form of life support for patients with severe respiratory failure with a potentially reversible cause, who has been refractory to conventional treatment.

It is estimated that between 200 – 300 patients will be accepted for treatment by this service annually, however, this is subject to significant variation in response to any incident, event or outbreak of disease that may result in the need for treatment by a specialist adult respiratory ECMO Centre.

3.3 Expected Significant Future Demographic Changes

Demographic changes are expected in line with general demographic changes in the population.

3.4 Evidence Base

The benefit of transferring patients with severe respiratory failure to centralised severe respiratory failure services providing ECMO was shown in the HTA funded 'CESAR' trial.

This trial showed that transferring adult patients with potentially reversible severe respiratory failure (Murray score equal or greater than 3.0 or pH < 7.20 due to hypercapnia despite optimal conventional management) to a centre with an ECMO-based management protocol significantly improved survival without severe disability at 6 months.

Additionally, a UK case-matched study undertaken during the influenza A (H1N1) pandemic in 2009 / 2010 demonstrated significantly lower mortality in patients who were referred for ECMO in one of the nationally designated ECMO respiratory centres.

References

Peek GJ, et al CESAR trial collaboration. Efficacy and economic assessment of conventional ventilatory support versus extracorporeal membrane oxygenation for severe adult respiratory failure (CESAR): a multicentre randomised controlled trial. Lancet. 2009 Oct 17;374(9698):1351-63.

Noah MA, et al Referral to an extracorporeal membrane oxygenation center and mortality among patients with severe 2009 influenza A (H1N1). JAMA. 2011 Oct 19;306(15):1659-68.

4. Outcomes and Applicable Quality Standards

4.1 Quality Statement – Aim of Service

The aim of the adult respiratory ECMO service is 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.

NHS Outcomes Framework Domains

Domain 1	**Preventing people from dying prematurely**	**x**
Domain 2	**Enhancing quality of life for people with long-term conditions**	**x**
Domain 3	**Helping people to recover from episodes of ill-health or following injury**	**x**
Domain 4	**Ensuring people have a positive experience of care**	**x**
Domain 5	**Treating and caring for people in safe environment and protecting them from avoidable harm**	**x**

4.2 Indicators Include:

Number	Indicator	Data Source	Outcome Framework Domain	CQC Key question
Clinical Outcomes				
101	% of referrals accepted for ECMO	Provider/ tracker	1,3,5	Effective
102	% of patients not accepted due to co-morbidities	Provider/ tracker	1,3,5	Effective
103	% of eligible referrals admitted for ECMO	Provider/ tracker	1,3,5	Effective
104	% of patients accepted that were assessed as unsuitable at retrieval	Provider/ tracker	1,3,5	Effective
105	% of accepted patients who died before retrieval	Provider/ tracker	1,3,5	Effective
106	% of patients who died following retrieval prior receiving ECMO	Provider/ tracker	1,3,5	Effective
107	% of eligible patients transferred to another centre for treatment due to bed shortages	Provider/ tracker	1,3,5	Effective
108	% of eligible patients transferred to another centre for treatment due to lack of retrieval team	Provider/ tracker	1,3,5	Effective
109	% of retrievals where team departs base within 90 minutes from the time the referral is accepted	Provider/ tracker	1,3,5	Effective
110	% patients surviving > 180 days	Provider/ tracker	1,3,5	Effective
111	% of patients surviving > 12months	Provider/ tracker	1,3,5	Effective

112	number of patients supported on ECMO	Provider/ tracker	1,3,5	Effective
113	number of patients with a duration of ECMO in excess of 30 days	Provider/ tracker	1,3,5	Effective
114	median /mean duration of ECMO	Provider/ tracker	1,3,5	Effective
115	% Patients who die within 48 hrs of admission	Provider/ tracker	1,3,5	Effective
116	% patients attending 6 month follow up	Provider/ tracker	1,3,5	Effective
Patient Experience				
201	There is information for families and carers	Self declaration	4	caring, responsive
202	The centre reviews feedback from parents/carers	Self declaration	4	caring, responsive
Structure and Process				
001	There is a specialist multidisciplinary team	Self declaration	1,2,3,5	well led, Effective safe
002	Staff receive specialist training	Self declaration	1.2,3,5	Effective safe
003	There are 24/7 rotas in place	Self declaration	1.2,3,5	Effective safe
004	There is MDT discussion of all patients	Self declaration	1,2,3,5	Effective safe
005	There is a 24/7 patient retrieval service	Self declaration	1,2,3,5	Effective safe
006	There is a 24/7 advice service for local health care professionals	Self declaration	1,2,3,5	Effective safe

007	There are clinical guidelines	Self declaration	1,2,3,5	Effective safe
008	There are patient pathways in place	Self declaration	1,2,3,5	Effective safe
009	There are local and national clinical governance meetings	Self declaration	1,2,3,5	Effective safe
010	The centre has a research and development strategy	Self declaration	1,2,3,5	Effective safe
011	The centre submits to the national registry	Self declaration	1,2,3,5	Effective safe

Detailed definitions of indicators, setting out how they will be measured, is included in schedule 6.

4.3 Commissioned providers are required to participate in annual quality assurance and collect and submit data to support the assessment of compliance with the service specification as set out in Schedule 4A-C

4.4 Applicable CQUIN goals are set out in Schedule 4D

5. Applicable Service Standards

5.1 Applicable Obligatory National Standards

Not applicable.

5.2 Other Applicable National Standards to be met by Commissioned Providers

National Standards which relate to Adult Critical Care are listed in the Service Specification for Adult Critical Care.

5.3 Other Applicable Local Standards

Not applicable.

6. Designated Providers

This service is commissioned from a restricted list of providers, each operating within a specified geographical network as indicated below. However, all providers are required to work together at time of clinical surge to provide treatment across the national population:

Guy's and St. Thomas' NHS Foundation Trust

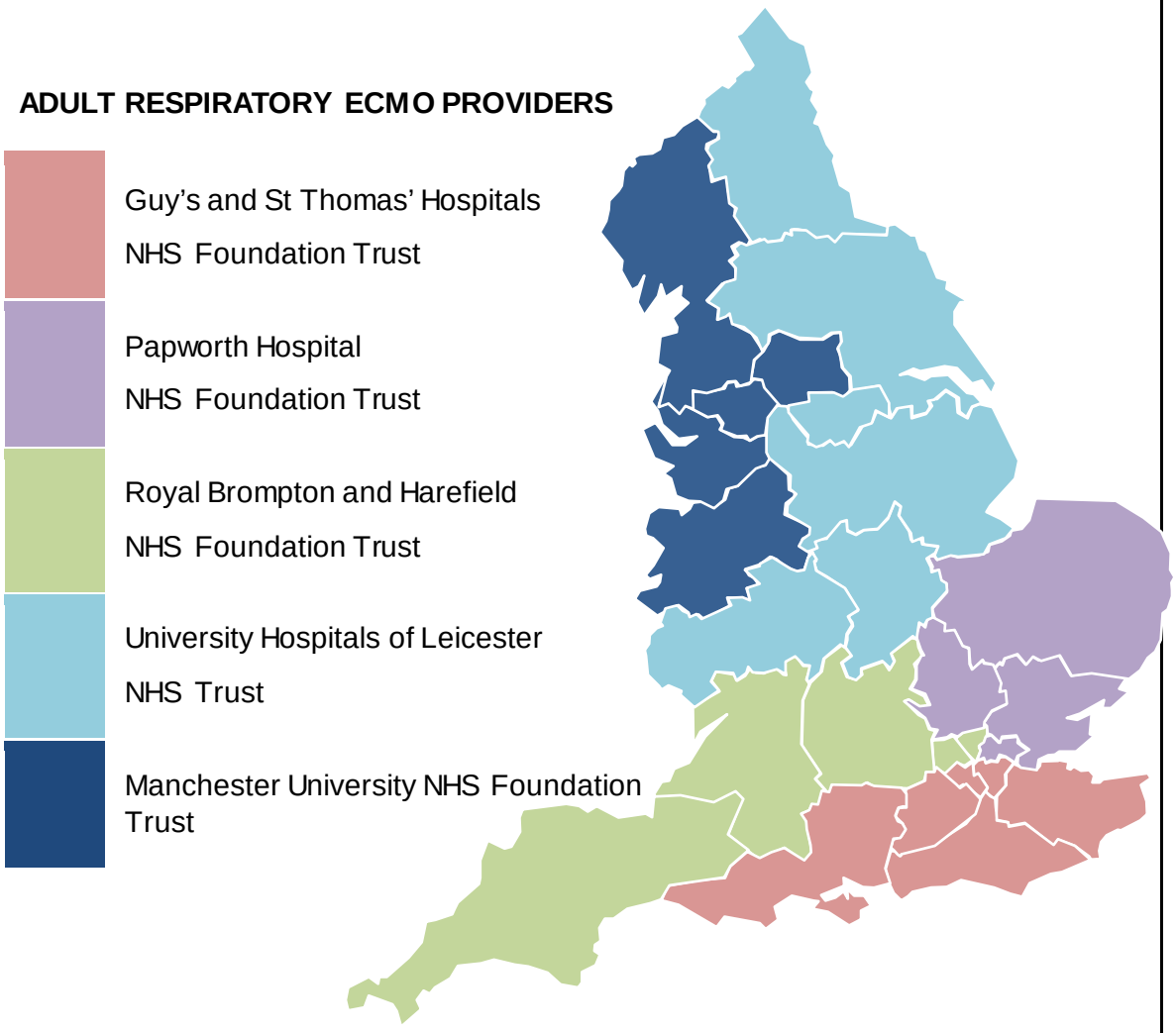
Papworth Hospital NHS Foundation Trust

Royal Brompton and Harefield NHS Foundation Trust

University Hospitals of Leicester NHS Foundation Trust

University of Manchester NHS Foundation Trust

NHS Grampian - Aberdeen Royal Infirmary **



** Aberdeen Royal Infirmary shall act as a satellite centre for patients confirmed as likely candidates for ECMO in consultation with University Hospitals Leicester.

7. Abbreviation and Acronyms Explained

The following abbreviations and acronyms have been used in this document:

ACC - Adult Critical Care

CCG – Clinical Commissioning Group

ECMO – Extra corporeal membrane oxygenation

EPRR – Emergency Preparedness, Resilience and Response

ODN – Operational Delivery Network

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