

Integrated Impact Assessment Report for Service Specifications			
Service Specification Reference Number	URN1707		
Service Specification Title	Adult Critical Care – Extra Corporeal Membrane Oxygenation (ECMO) for Respiratory Failure in adults Proposal <u>for routine commission</u> (source A3.1)		
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About this Impact Assessment: instructions for completion and explanatory notes

- Each section is divided into themes.
- Each theme sets out a number of questions.
- All questions are answered by selecting a drop down option or including free text.
- Free text boxes are provided to enable succinct relevant commentary to be added which explains the rationale for response or assumption. Please limit responses to 3 sentences of explanatory text.
- Data in this document is either drawn from one of the relevant service specification documents or a source for the information is provided.
- Where assumptions are included where data is not available, this is specified.

Section A - Activity Impact			
A1 Current Patient Population & Demography / Growth			
A1.1 Prevalence of the disease/condition.	Advanced support for respiratory failure was required in 66816 patients accounting for 39.5% of admissions to ITU in the UK (ICNARC 2016-17). Of these patients only 2-300 require admission for ECMO (0.3-0.4%) of ventilated adult ICU patients. Source: Service Specification Proposition section 3.1		
A1.2 Number of patients currently eligible for the service according to the proposed service specification commissioning criteria.	200-300 annually Source: Previous Annual Activity data Please specify Click here to enter text.		
A1.3 Age group for which the service is proposed according to the service specification commissioning criteria.	Adults Please specify Note: 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.		
A1.4 Age distribution of the patient population eligible according to the proposed service specification commissioning criteria	16 years and over if relevant Source: Previous Annual Activity data Please specify There will on occasion be clinically appropriate to manage younger patients within the adult service (see 1.3)		

A1.5 How is the population currently distributed geographically?	Unevenly			
	If unevenly, estimate regional distribution by %:			
	North	21%		
	Midlands & East	31%		
	London	16%		
	South	31%		
	Source: Activity analy	ysis for geographical mapping completed 2016 xt.		
A2 Future Patient Population & Demography				
A2.1 Projected changes in the disease/condition epidemiology, such as incidence or prevalence (prior to applying the new service specification) in 2, 5, and 10 years?	from any incident, ever for treatment by a specific expected seasonal value the winter months.	o be constant - subject to significant variation resulting ent or outbreak of disease that may result in the need ecialist adult respiratory ECMO Centre. There is an ariation with predominance of admissions occurring in cification proposition section 3.1		
A2.2 Are there likely to be changes in demography of the patient population and would this impact on activity/outcomes?	No Please specify Click here to enter tex Source: Service specify	xt. cification proposition section 6/other		
A2.3 Expected net increase or decrease in the number of patients who will be eligible for the service, according to the proposed		es ONS population changes. se or decrease in number of eligible adults receiving		

service specification commissioning criteria, per year in years 2-5 and 10?	ECMO for severe respiratory failure will be influenced by the prevalence of respiratory illness in the community (e.g. influenza), and therefore number of patients receiving ECMO for respiratory failure will be subject to both seasonal and annual variation.		
	YR2 +/-	+10	
	YR3 +/-	+5	
	YR4 +/-	+6	
	YR5 +/-	+6	
	YR10 +/-	+30	Source: Service specification proposition section 3.1
Are these numbers in line with ONS growth assumptions for the age specific population? If not please justify the growth assumptions made.	Yes Yes		
A3 Activity			
A3.1 What is the purpose of new service specification?	Revision to an existing published service specification *PSSAG (Prescribed Specialised Services Advisory Group) Please specify Click here to enter text.		
A3.2 What is the annual activity associated with the existing pathway for the eligible population?	200-300 patients Source: Previous	Annual Activity d	ata Please specify

	Click here to enter text.
A3.3 What is the estimated annual activity associated with the proposed service specification proposition pathway for the eligible population?	200-300 patients Source Previous Annual Activity data Please specify Click here to enter text.

A4 Patient Pathway

A4.1 Patient pathway

Describe the current patient pathway and service.

Extracorporeal membrane oxygenation (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 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)
- Provide follow-up care for patient and their families
- End of life care

Source: Service Specification

A4.2. What are the current service access and stopping 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. Source: Service Specification
A4.3 What percentage of the total eligible population are: a) Referred b) Meet any existing criteria for care c) Considered to meet any existing exclusion criteria	If not known, please specify Click here to enter text. a) enter % b) 30% c) 70% Source: Activity returns from the service identify that of those patients referred, 30% are accepted for treatment and 70% do not meet the exiting treatment criteria.
 A4.4 What percentage of the total eligible population is expected to: a) Be referred to the proposed service b) Be eligible for care according to the proposed criteria for the service c) Take up care according to the proposed criteria for the service d) Continue care according to the proposed criteria for the service? 	If not known, please specify The proposed service is the same as the existing service. a) No change b) No change c) No change d) No change Source: required
A4.5 Specify the nature and duration of the proposed new service or intervention.	Time limited For time limited services, specify frequency and/or duration. One off admission in response to acute illness. ECMO treatment median length of stay 10 days, mean 14 days. This is unchanged from the existing service Source: required

A5 Service Setting				
A5.1 How is this service delivered to the patient?	Select all that apply:			
	Emergency/Urgent care	Emergency/Urgent care attendance		
	Acute Trust: inpatient		\boxtimes	
	Acute Trust: day patient			
	Acute Trust: outpatient			
	Mental Health provider: i	npatient		
	Mental Health provider: o	outpatient		
	Community setting			
	Homecare			
	Other			
	Please specify: Click here to enter text.			
A5.2 What is the current number of contracted providers for the	NORTH	1		
eligible population by region?	MIDLANDS & EAST	2		
	LONDON	2		
	SOUTH	number		
	The 2 providers in Londor work as part of a natio		-	ion of the South. All provid ave designated geographic

	areas that they cover.	
A5.3 Does the proposition require a change of delivery setting or capacity requirements?	No Please specify: Click here to enter text. Source: required	
A6 Coding		
A6.1 Specify the datasets used to record the new patient pathway activity.	Select all that apply: Note: the patient pathway is unchanged from current service.	
*expected to be populated for all commissioned activity	Aggregate Contract Monitoring *	
	Patient level contract monitoring	
	Patient level drugs dataset	
	Patient level devices dataset	
	Devices supply chain reconciliation dataset	
	Secondary Usage Service (SUS+)	
	Mental Health Services DataSet (MHSDS)	
	National Return**	
	Clinical Database**	
	Other**	\boxtimes
	**If National Return, Clinical database or other	selected, please specify:

	Highly Specialised commissioning Monthly dat	a return.	
A6.2 Specify how the activity related to the new patient pathway will	Select all that apply:		
be identified.	OPCS v4.8		
	ICD10		
	Service function code		
	Main Speciality code		
	HRG		
	SNOMED		
	Clinical coding / terming methodology used by clinical profession		
A6.3 Identification Rules for Drugs: How are any drug costs captured?	Not applicable If already specified in the current NHS England Drug / Devices List, please		
Thow are any drug cooks captured:	specify drug name and indication for all that apply: Click here to enter text.		
	If drug(s) NOT already been specified in the cultist please give details of action required and discussed with the pharmacy lead: Click here to enter text.		
A6.4 Identification Rules for Devices:	Not applicable		
How are device costs captured?	If device(s) covered by an existing category of HCTED please specified Device Category (as per the National Tariff Payment System Guida for all that apply:		
	Click here to enter text.		
	If device(s) not excluded from Tariff nor covered	ed within existing National or	

Local prices please specify details of action required and confirm that this has been discussed with the HCTED team. Click here to enter text.
Already correctly captured by an existing specialised service line (NCBPS code within the PSS Tool) If activity costs are already captured please specify the specialised service code and description (e.g. NCBPS01C Chemotherapy). NCBPS29M respiratory If activity costs are already captured please specify whether this service needs a separate code. No If the activity is captured but the service line needs amendment please specify whether the proposed amendments have been documented and agreed with the Identification Rules team. Click here to enter text. If the activity is not captured please specify whether the proposed identification rules have been documented and agreed with the Identification Rules team. Choose an item.
None Please specify No new data requirements

A7.2 Business intelligence	<u>No</u>
Is there potential for duplicate reporting?	If yes, please specify mitigation:
	Click here to enter text.
A7.3 Contract monitoring	Yes
Is this part of routine contract monitoring?	If no, please specify contract monitoring requirement:
	Click here to enter text.
A7.4 Dashboard reporting	<u>No</u>
Specify whether a dashboard exists for the proposed service?	If yes, specify how routine performance monitoring data will be used for dashboard reporting.
	Click here to enter text.
	If no, will one be developed?
	Yes, the new indicators within the revised specification will be used to produce a dashboard.
A7.5 NICE reporting	<u>No</u>
Are there any directly applicable NICE or equivalent quality	If yes, specify how performance monitoring data will be used for this
standards which need to be monitored in association with the new	purpose.
service specification?	Click here to enter text.
Section E	B - Service Impact
B1 Service Organisation	
B1.1 Describe how the service is currently organised? (i.e. tertiary centres, networked provision etc.)	The service is currently delivered through a network of 5 highly specialised providers. Each provider has a designated geographical within which they operate, but they also work together at time of clinical surge to provide treatment across the national population.

	Source: required		
B1.2 Will the specification change the way the commissioned service is organised?	No Please specify: Click here to enter text. Source: required		
B1.3 Will the specification require a new approach to the organisation of care?	No change to delivery of car Please specify: Click here to enter text.	<u>re</u>	
B2 Geography & Access			
B2.1 Where do current referrals come from?	Select all that apply:		
	GP		
	Secondary care	\boxtimes	
	Tertiary care	\boxtimes	
	Other		
	Please specify: Click here to enter text.		
B2.2 What impact will the new service specification have on the sources of referral?	No impact Please specify: Click here to enter text.		

B2.3 Is the new service specification likely to improve equity of access?	No impact Please specify: Click here to enter text. Source: Equalities Impact Assessment
B2.4 Is the new service specification likely to improve equality of access and/or outcomes?	No impact Please specify: Click here to enter text. Source: Equalities Impact Assessment
B3 Implementation	
B3.1 Will commissioning or provider action be required before implementation of the proposition can occur?	No action required Please specify: Click here to enter text.
B3.2 Time to implementation: Is a lead-in time required prior to implementation?	No - go to B3.4 If yes, specify the likely time to implementation: Enter text
B3.3 Time to implementation: If lead-in time is required prior to implementation, will an interim plan for implementation be required?	No - go to B3.4 If yes, outline the plan: Click here to enter text.
B3.4 Is a change in provider physical infrastructure required?	No Please specify: Click here to enter text.

B3.5 Is a change in provider staffing required?	No Please specif Click here to	•		
B3.6 Are there new clinical dependency and/or adjacency requirements that would need to be in place?	No Please specif Click here to	•		
B3.7 Are there changes in the support services that need to be in place?	No Please specif Click here to	•		
B3.8 Is there a change in provider and/or inter-provider governance required? (e.g. ODN arrangements / prime contractor)	No Please specifical Click here to	•		
B3.9 Is there likely to be either an increase or decrease in the number of commissioned providers? If yes, specify the current and	No change Please complete the table:			
estimated number of providers required in each region	Region	Current no. of providers	Future State expected range	Provisional or confirmed
	North	1		select
	Midlands & East	2		select
	London	2		select
	South	0		select
	Total	5		select

	Please specify: Click here to enter text.				
B3.10 Specify how revised provision will be secured by NHS	Select all that apply:	Select all that apply:			
England as the responsible commissioner.	Publication and notification of new service specification				
	Market intervention required				
	Competitive selection process to secure increase or decrease provider configuration				
	Price-based selection process to maximise cost effectiveness				
	Any qualified provider				
	National Commercial Agreements e.g. drugs, devices				
	Procurement				
	Other				
	Please specify: Click here to enter text.				
B4 Place-based Commissioning					
B4.1 Is this service currently subject to, or planned for, place-based commissioning arrangements? (e.g. future CCG lead, devolved commissioning arrangements, STPs)	No Please specify: Click here to enter text.				
Section C	- Finance Impact				

C1 Tariff/Pricing					
C1.1 How is the service contracted and/or charged?		Select all that apply:			
Only specify for the relevant section of the patient pathway		Not separately charged – part of local or national tariffs	\boxtimes		
	Drugs	Excluded from tariff – pass through			
		Excluded from tariff - other			
		Not separately charged – part of local or national tariffs	\boxtimes		
	Devices	Excluded from tariff (excluding ZCM) – pass through			
	Devices	Excluded from tariff (excluding ZCM) – other			
		Via Zero Cost Model			
		Paid entirely by National Tariffs			
		Paid entirely by Local Tariffs	\boxtimes		
	Activity	Partially paid by National Tariffs			
		Partially paid by Local Tariffs			
		Part/fully paid under a Block arrangement			
		Part/fully paid under Pass-Through arrangements			
		Part/fully paid under Other arrangements			
C1 2 Drug Costs	Not applied	iblo			
C1.2 Drug Costs Where not included in national or local tariffs, list each drug or combination, dosage, quantity, list price including VAT if applicable and any other key information e.g. Chemotherapy Regime. NB discounted prices or local prices must not be included as these	Not applica	IDIC			

are subject to commercial confidentiality and must not be disclosed.	
C1.3 Device Costs Where not included in national or local tariff, list each element of the excluded device, quantity, list or expected price including VAT if applicable and any other key information. NB: Discounted prices or local prices must not be included as these are subject to commercial confidentiality and must not be disclosed.	Not applicable
C1.4 Activity Costs covered by National Tariff List all the HRG codes, HRG descriptions, national tariffs (excluding MFF), volume and other key costs (e.g. specialist top up %)	Not applicable
C1.5 Activity Costs covered by Local Tariff List all the HRGs (if applicable), HRG or local description, estimated average tariff, volume and any other key costs. Also indicate whether the Local Tariff(s) is/are newly proposed or established and if newly proposed how is has been derived, validated and tested.	No change
C1.6 Other Activity Costs not covered by National or Local Tariff Include descriptions and estimates of all key costs.	Not applicable
C1.7 Are there any prior approval mechanisms required either during implementation or permanently?	No Please specify: Click here to enter text.
C2 Average Cost per Patient	

C2.1 What is the estimated cost per patient to NHS England, in years 1-5, including follow-up where required?	Not applicable existing tariff	le – the updated service specification has no impact
	YR1	enter number.
	YR2	enter number.
	YR3	enter number.
Are there any changes expected in year 6-10 which would impact	YR4	enter number.
the model?	YR5	enter number.
	If yes, please	e specify:
	Click here to	enter text.
C3 Overall Cost Impact of this Service specification to NHS En	gland	
C3.1 Specify the budget impact of the proposal on NHS England in	gland Cost neutra	<u>l</u>
	Cost neutra Please spec	<u>I</u> ify:
C3.1 Specify the budget impact of the proposal on NHS England in	gland Cost neutra	<u>I</u> ify:
C3.1 Specify the budget impact of the proposal on NHS England in	Cost neutra Please spec	ify: enter text.

C4.1 Specify the budget impact of the proposal on other parts of the NHS.	Budget impact for CCGs: No impact on CCGs Budget impact for providers: Cost neutral Please specify: Click here to enter text.
C4.2 Taking into account responses to C3.1 and C4.1, specify the budget impact to the NHS as a whole.	Cost neutral Please specify: Click here to enter text.
C4.3 Where the budget impact is unknown set out the reasons why this cannot be measured	Not applicable
C4.4 Are there likely to be any costs or savings for non-NHS commissioners and/or public sector funders?	No Please specify: Click here to enter text.
C5 Funding	
C5 Funding C5.1 Where a cost pressure is indicated, state known source of funds for investment, where identified, e.g. decommissioning less clinically or cost-effective services.	Not applicable

C6.1 What are the material financial risks to implementing this service specification?	None – no material changes to the current service specification		
C6.2 How can these risks be mitigated?	Not applicable		
C6.3 What scenarios (differential assumptions) have been explicitly tested to generate best case, worst case and most likely total cost scenarios?	Not applicable – no change to existing service		
C6.4 What scenario has been approved and why?	Not applicable		
C7 Value for Money			
C7.1 What published evidence is available that the service is cost	There is no published evidence of cost-effectiveness		
effective as evidenced in the evidence review?	Please specify:		
	Click here to enter text.		
C7.2 Has other data been identified through the service	Select all that apply:		
specification development relevant to the assessment of value for money?	Available pricing data suggests the service specification is equivalent cost compared to current/comparator service specification		
	Available pricing data suggests the service is lower cost compared to current/comparator treatment		
	Available clinical practice data suggests the new service specification has the potential to improve value for money		
	Other data has been identified		
	No data has been identified	\boxtimes	

	The data supports a high level of certainty about the impact on value	
	The data does not support a high level of certainty about the impact on value	
	Please specify: Click here to enter text.	
C8 Non-Recurrent Costs		
C8.1 Are there non-recurrent revenue costs associated with this service specification?	No If yes, please specify and indicate whether these would be incurred passed through to NHS England: Not applicable If the costs are to be passed through to NHS England please indicat whether this has been taken into account in the budgetary impact. Choose an item.	
C8.2 Are there any non-recurrent provider capital costs associated with the service specification?	No If yes, please specify and indicate with there is a separate source of funding identified (commissioners cannot reimburse capital costs). Not applicable	: