英国における EMCO センター（Severe respiratory failure centre）設立に関する調査

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１） 訪問機関

英国訪問期間：
１）2013/12/04 ~ 2013/12/08
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２）調査内容

Dr. Nicholas Barrett

取材方法：
事前に連絡してあった取材内容について，作成されていたファイル（別添）を基に口頭による取材を行った

取材内容：
イントロダクション：
イギリスは，イングランド、スコットランド、ウェールズ、北アイルランドの４つの国（county） から構成されるが，現在はグレートブリテンおよび北アイルランド連合王国と呼ばれる．今回，取材対象となった医療のセンター化については，イングランドが対象であり，人口にして 5300 万人あまり，面積にして日本の国土の 35%に当たる 13 万 km2 が対象となる．
イギリスは戦後、国民保健サービス法を制定し、医療保障には財源を主として租税に求める国営医療方式を採用している点が特徴であり，我が国を含めた西洋諸国は，医療保障に保険制度を取っている点で大きく異なる．
イギリスでは原則として全国民が無料で，医療サービスを受けることができる．これが有名な『国民保険サービス (National Health Service、以下 NHS と呼ぶ)』であり，他の自由主義諸圏の医療制度とは異なった特徴を呈している．すなわち，国営医療であり，国営病院の病床数は全体の 70%で，そこで働く医師，看護師等は国家公務員である．これを規定しているのが 1946 年に成立し 1948 年から施行された NHS 法（National Health Service Act, 1946）である．今回の取材では，医療提供のセンター化について NHS がどのように関与したのかについては，詳細が掴めておらず，医療保障システムという視点で新たな取材が必要である．

経緯；
2009 年にイングランドを襲った H1N1 インフルエンザによる呼吸不全への対応について，NHS とイングランド全体の ICU 運営者の間で大きな議論が交わされた．これは，やく 1600 床の ICU ベッドの過半数である 851 床がインフルエンザによる呼吸不全で占拠されたことに端を発する．その結果，NHS と ICU 運営者の間で患者大量発生時の対応を予め決めておくことをゴールとしたものであった．

その結果，以下のことが決められた．
・ イングランド全体を４つのゾーンに分け，５つのセンター病院を指定すること．
・ このセンター病院で呼吸不全に対する ECMO を行うこと．
・ 調整は中央で行うこと．
・ 臨時の処置であること．
・ トリアージの条件を決めたこと．
・ 患者搬送は，通常の救急車を用いること．
などが話し合われた．
その結果，５つのセンターにおける H1N1 呼吸不全の死亡率とその他の施設における死亡率には２倍近い成績の差が生まれたことで， ad hoc で置かれた施設のセンター化が有効であったことが証明された (Noah, JAMA 2011)．同時に，年間に治療を行

っている患者数によって予後が決定されていることも証明され，予後の改善にはセンター化による患者の集中が不可欠であるという結論が得られた．

そこで，地域における重症呼吸不全治療センター（severe respiratory failure center: SRF center） を構成することが決定された．センター病院での治療は NHS からの委託であること，Department of Health が仕切ること，病院が仕切ることを明確にすること．などが決められた．
Commissioning process: 委託の方法
治療の基準の確定は 3 つのフェーズで行われた：pre-qualification questionnaire, tender document, Viva の 3 段階である．

Dr. Giles J Peek

可逆的な肺病変を持つ重症呼吸不全の治療に当たって，通常の人工呼吸管理を行った場合と ECMO による治療が可能な施設に搬送した上で，治療を継続した場合を比較した他施設研究を行ったのが Dr. Giles J Peek である．
今回の取材では，その臨床研究に加えて Glenfield Hospital の ECMO センターの見学も兼ねて訪れた．
ECMO のためのセンターを作ったわけではなく，重症呼吸不全の治療の選択肢の一つに ECMO を有する施設の方が，そうした機能のない施設に比べて成績が圧倒的に良いことが明らかであり，重症呼吸不全のためのセンター化が必須という結論に達している．

Department of Health

センター化に際して、どの様な議論があったのかについて調査を行った．
その結果，施設における治療内容や設備に加えて，患者密度がある程度以上ないと診療の質が維持できないことが明らかとなり，施設登録は当初，施設の希望で行ったが，その絞り込みについては詳細な調査によった．
基本的に診療費は英国では，全て DOH よりの資金で NHS が行っているため，センターとして認められなかった施設には診療費が支払われないため，効率的なセンター化が可能であった．

結論：
- 施設見学から得られた点：
  - イングランド全土を４つの地域とし５つの重症呼吸不全センターでカバーしている．このため，１施設当たりの呼吸不全に対する ECMO 患者数は年間 50 例以上を維持するのに十分な患者数が該当する．
  - 地域の住民は該当するセンターに搬送されるが，これは当該センターのキャパシティーを超えていない限り厳守されている．つまり，患者や担当医の自由意志でセンターを選択することはできない．
  - センター毎の治療成績をはじめとする診療内容は厳密に評価され，追跡されるため，診療の質は常に担保されている仕組みである．

- Department of Health / National Health Service から得られた点：
  - 本邦では，ハード面（施設，機器など）でもソフト面（マンパワーと教育な

ど）でも，現時点で世界標準の治療を十分な患者密度で提供できる施設はない．先ず，教育・啓蒙を徹底して図り，重症呼吸不全に対する治療が ECMO も含めて十分に普及させることが最優先事項である．

- 数年後に，啓蒙が済み，標準的治療が普及した段階で，センター化に向けた絞り込みを考えるべきであり，最初からセンター化は非常に困難であると考える．
- センター化を図るまでに行うべき事業としては，啓蒙・教育事業であり，国によるサポートが必須のことと考えられる．

３）英国における重症呼吸不全に対する ECMO を含めた治療センター設立の要件

必要性：
急性呼吸不全 (ARDS) 時の肺の代用となる ECMO は，様々な原因（肺炎や外傷など）による致死的な ARDS 症例に用いられるが，ARDS は肺水腫，治療不応の低酸素血症，高二酸化炭素血症，そして肺コンプライアンスの低下という肺の炎症反応を特徴とする．
ECMO は治療法というよりは生命維持の手段であり，患者の恒常性を維持することで治癒に必要な時間を稼ぐことが目的で用いられる．ARDS による呼吸不全に対する ECMO は５日から１４日間程度の治療期間を必要とするが，１４日間以上を要する症例も少なくない．心機能が重篤でない限り，静脈・静脈 ECMO (VV) が好まれるが，心不全時には静脈・動脈 ECMO (VA) が用いられることもある．ECMO 中には体外循環回路を用いるため，ヘパリン等の抗凝固薬が必要であり，頭蓋内出血，頭部外傷，手術直後，消化管出血を合併する場合には，ECMO の導入は禁忌となる．

ARDS の病態が可逆的であることが ECMO の条件となるが，肺移植へのブリッジングは条件とならない．

ARDS に対する ECMO を含む治療は，誰もが標準化された治療法にアクセス可能であることが必要である．そのためには，ECMO を使用した搬送を含めて２４時間，３６５日，治療センターは治療を提供する必要がある．
現時点で，英国には５つの国立センターがあり，成人の重症呼吸不全に ECMO を含めた治療を提供している．それぞれのセンターは，成人の集中治療が可能であるとともに，集中治療ネットワーク (Critical Care Operational Delivery Network) のメンバーである必要がある．

エビデンスと主要文献：
最初の ECMO 治療は，1970 年代に米国で行われたが，生存率の改善にはつながらなかった．1980 年代には ECCOR と呼ばれる新たな ECMO システムを用いた臨床研究も行われたが予後は改善されなかった．ECMO 症例は，現在，肺保護換気と呼ばれる換気条件では人工呼吸されなかったことを含めて，現在の標準的な集中治療が行われなかったことが予後を改善しなかった原因と考えられる．
一方，CESAR trial (2001-2006) は，可逆的な重症呼吸不全症例を ECMO による治療も可能な施設に搬送することで，６ヶ月死亡率を劇的に改善することを証明した．さらに，H1N1 インフルエンザのパンデミック時には，国立センター（ ECMO 治療が可能）に搬送された症例の方が，死亡率が改善されることが証明されている．

- Zapol WM, Snider MT, Hill JD et al. Extracorporeal membrane oxygenation in severe acute respiratory failure. A randomised prospective study. JAMA 1979; 242:2193-2196.
- Morris AH, Wallace CJ, Menlove RL, et al. Randomized clinical trial of pressure-controlled inverse ratio ventilation and extracorporeal CO2 removal for adult respiratory distress syndrome. American Journal or Respiratory Critical Care

Medicine 1994; 149:295-305.
- Peek GJ, Moore HM, Moore N et al Extracorporeal membrane oxygenation for adult respiratory failure. Chest. 1997 Sep;112(3):759-64.
- Peek GJ, Mugford M, Tiruvoipati R 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 randomized controlled trial. Lancet. 2009 Oct 17;374(9698):1351-63.
- Moronke A. Noah, Giles J. Peek, Simon J. Finney et al Extracorporeal Membrane Oxygenation for Severe Adult Respiratory Failure Secondary to 2009 H1N1 Influenza A: a case-matched study. JAMA. 2011; 306(15):1659-68

展望：
本診療サービスの目的は，通常の治療法に抵抗性の 16 歳以上の成人呼吸不全について，診療を公平に提供し，適切なタイミングで国立 ECMO センターに収容できることにある.

各施設は,『ECMO を用いた重症呼吸不全に対する治療』(National Standards for the Nationally Designated Service: Extracorporeal Membrane Oxygenation (ECMO) for Patients with Potentially Reversible Severe Respiratory Failure) という国の定めた治療法を提供することが条件である. 具体的な診療内容については，厳密な調査を行う.

成人の呼吸不全に対する ECMO 治療は，以下の条件が必須：
- 関連病院に ECMO 治療の周知
- 治療に適応のある症例の受け入れ
- 関連施設で，専門医による評価
- 48 時間以内に ECMO センターでの評価
- 標準的なクリニカルパスによる ECMO 治療の提供
- ECMO 離脱後の治療
- 終末期医療

ECMO 離脱後には，紹介のあった施設に患者を搬送するか，あるいは居住地域に近く，集中治療が可能な施設への搬送を考慮する.

4）ECMO センターの基準

可逆的と想定される重症呼吸不全に対する ECMO の導入に関する英国における基準について公表されている。

これは，ECMO センターにおける診療の基準を定めたものである.
NHS England は，特別な治療を提供する病院については，提供される診療が安全であること，有効であること，患者優先の診療であること，ならびに高い質の診療が行われていることが条件である.

NHS England

D16

NHS STANDARD CONTRACT

ADULT CRITICAL CARE- ECMO FOR Respiratory Failure

SCHEDULE 2 – 14/15 SERVICE SPECIFICATION

Service Specification No.	**D16**
Service	**Adult Critical Care – ECMO for Respiratory Failure**
Commissioner Lead	
Provider Lead	
Period	**12 months**
Date of Review	

1. Population Needs

1.1 National/local context and evidence base

National 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, refractory hypercapnoea and reduced lung compliance. ECMO may also be used to support patients with other causes of potentially reversible severe respiratory failure.

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 of between five and fourteen days. Some patients may require ECMO support beyond fourteen days. Venous-venous ECMO (VV) is preferred for adult respiratory failure when cardiac function is adequate or mildly depressed. Hybrid VVA or VA ECMO (Venous-Arterial) may be necessary

for some patients. Patients on ECMO may require anticoagulation with heparin or an alternative anticoagulant due to use of an extracorporeal circuit. Therefore ECMO might be contraindicated in patients with a recent intracranial bleed, trauma (particularly with head injury), or recent surgery or bleeding from the GI tract.

ECMO is a bridge to recovery for these patients, and reversibility of the presenting condition is a key-criteria for inclusion in the service. Bridging to lung transplant is not part of this service specification.
The service is delivered through a number of 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 treatment / consideration of ECMO. Centres must be able to provide safe retrieval 24 hours per day, 365 days per year, including mobile ECMO for patients who are clinically eligible.

There are currently 5 designated National Centres providing ECMO for severe respiratory failure to patients of 16years or older. Each centre must also fulfil the separate service specification for adult critical care and be members of a Critical Care Operational Delivery Network.

Evidence Base and Key Publications

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. This also failed to show benefit. Patients enrolled in these trials were mechanically ventilated in a manner that is now considered to be further injurious to the lung and do not apply to current critical care practice.

By contrast, a case control study from Leicester reported in 1997 suggested benefit. The subsequent CESAR trial (2001-2006) demonstrated that transferring adult patients with potentially reversible severe respiratory failure whose Murray score was equal to or greater than 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 significantly improved survival without severe disability at 6 months. Further, more a case-matched study undertaken during the influenza A (H1N1) pandemic in 2009 / 2010 demonstrated lower mortality in patients transferred to the nationally designated ECMO-accredited respiratory failure centres. The majority of patients in these centres underwent ECMO.

References

- Zapol WM, Snider MT, Hill JD et al. Extracorporeal membrane oxygenation in severe acute respiratory failure. A randomised prospective study. JAMA 1979; 242:2193-2196.

- Morris AH, Wallace CJ, Menlove RL, et al. Randomized clinical trial of pressure-controlled inverse ratio ventilation and extracorporeal CO_2 removal for adult respiratory distress syndrome. American Journal or Respiratory Critical Care Medicine 1994; 149:295-305.

- Peek GJ, Moore HM, Moore N et al Extracorporeal membrane oxygenation for adult respiratory failure. Chest. 1997 Sep;112(3):759-64.

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

- Moronke A. Noah, Giles J. Peek, Simon J. Finney et al Extracorporeal Membrane Oxygenation for Severe Adult Respiratory Failure Secondary to 2009 H1N1 Influenza A: a case-matched study. JAMA. 2011; 306(15):1659-68

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

This service specification dovetails into and underpins the work programmes for the Adult Strategic Clinical Networks, in particular Cancer, Cardiovascular Disease, Maternity services and the Major Trauma programme of work. This service specification encompasses all patients aged 16years and above who develop severe respiratory failure which is refractory to conventional ventilation, irrespective of the cause of the respiratory failure.

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

Key Service Outcomes

1. Participation in the Extracorporeal Life Support Organisation (ELSO) database which provides bench-marked outcomes including survival and suite of morbidity measures.
2. Compliance with tidal volume below 6ml/kg.
3. Proportion of patients with an assessment of long term outcome measures following ECMO eg Quality of Life between 3 and 12 months after ECMO.
4. Measurement of numbers of patients who are not accepted for ECMO due to lack of capacity (expressed as % of referred patients).
5. Referring critical care units (or appropriate designated unit in local Adult Critical Care ODN) to receive back their patients within 48hours of decision to repatriate by the ECMO centre.

The thresholds and methods of measurement for each indicator are detailed in appendix 2. These outcomes will be assessed as part of the annual peer review process which the designated sites are planning (appendix 3). Data on repatriation within 48 hours of the decision to transfer for care closer to home will be collected from the receiving units ICNARC CMP dataset (outcome5). ELSO international comparator data is shared with NHS England commissioners annually. In addition 6

monthly updates are also provided.

Other Patient and Service Outcome measures

1. Meet the national standards for respiratory ECMO, as a minimum, as detailed in the current ECMO tender (appendix 1).

2. Have the expertise to manage patients with potentially reversible severe respiratory failure through the use of the most up-to-date clinical practice, including but not limited to ECMO.

3. Collaborate with other nationally commissioned providers of adult ECMO to minimise potential delays in patients accessing respiratory ECMO care and provide "surge" capacity at times of escalation. This will be facilitated by NHS England and the National Clinical Director for Critical Care and Emergency Preparedness and Resilience.

3. Scope

3.1 Aims and objectives of service

- The aims of this service specification are to ensure equity of access, and timely admission and discharge to and from the nationally designated ECMO centres for all appropriate patients of 16 years or older with respiratory failure refractory to conventional therapy..

3.2 Service description/care pathway

.
Each provider must comply with the National Standards for the Nationally Designated Service: Extracorporeal Membrane Oxygenation (ECMO) for Patients with Potentially Reversible Severe Respiratory Failure. Peer review exists between Providers as detailed in Appendix 3.

The adult respiratory ECMO service care pathway encompasses:
- Provision of advice to referring hospitals
- Referral and acceptance of patients who fulfil eligibility criteria for service
- Specialist assessment at referring site and retrieval
- Assessment in ECMO centre (up to a maximum of 48 hours)
- Treatment; 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 referring critical care team or an appropriately designated adult critical care unit in the geographical vicinity of the patient's home. Such designation, if required, will be undertaken by the patient's Critical Care ODN. Repatriation should occur within 48hours of the decision to repatriate.

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.

NHS England does not commission:
- Conventional care (including critical care) once a patient is discharged from the adult respiratory ECMO care pathway. This is funded by the patient's CCG.
- Repatriation transport.

3.3 Population covered

Patients are referred from Intensive Care Units of England, Wales, Scotland and Northern Ireland. Additionally the UK has a reciprocal arrangement for international referrals with European countries,most notably Sweden. The service is to be available 24 hours a day, 365 days per year and covers all patients with refractory respiratory failure aged 16 years and over.

3.4 Any acceptance and exclusion criteria and thresholds

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 or who have failed a lung protective ventilatory strategy.
Providers will provide advice to referring hospitals on the management of patients with severe acute respiratory failure.
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 above, or uncompensated hypercapnea 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 any contraindication to continuation of active treatment.
Relative exclusions to ECMO treatment are:
- use of high pressure (plateau pressure > 30 cmH_2O) and/or high FiO_2 (> 0.8) ventilation for more than 7 days (168 hours)
- intracranial bleeding
- contraindication to limited heparinisation

3.5 Interdependencies with other services/providers

Provision of ECMO should be within a tertiary intensive care units which has expertise in the specialist management of severe respiratory failure and is part of the local critical care ODN. There must be co-location of cardiac and thoracic surgery. This service specification is a supplement to the D16 ACC service specification and as such ECMO centres must comply in full with the standards, outcomes and the interdependencies detailed in that specification.

Specific notifiable diseases should be reported to Local Authority under the Health Protection (Notification) Regulations 2010.

It is expected that providers are always able to maintain an adult respiratory ECMO capability, despite competing pressures from other services. NHS England will monitor service activity and notify the National Clinical Director for Emergency Preparedness and Critical Care when the whole service is under capacity pressure.

4. Applicable Service Standards

4.1 Applicable national standards e.g. NICE

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

Additional national service standards for adult respiratory ECMO centres are listed in appendix 1 of this document (National Standards for the Nationally Designated Service: Extracorporeal Membrane Oxygenation (ECMO) for Patients with Potentially Reversible Severe Respiratory Failure)

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).

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4.2 Applicable standards set out in Guidance and/or issued by a competent body (e.g. Royal Colleges)

Standards issued by Professional Societies which relate to Adult Critical Care are listed in the Service Specification for Adult Critical Care.

5. Applicable quality requirements and CQUIN goals

These are in the process of being developed and will be inserted once agreed.

5.1 Applicable quality requirements (See Schedule 4 Parts A-D)

5.2 Applicable CQUIN goals (See Schedule 4 Part E)
6. Location of Provider Premises
The Provider's Premises are located at: Guy's and St Thomas' NHS Foundation Trust Papworth Hospital NHS Foundation Trust Royal Brompton and Harefield NHS Foundation Trust University of South Manchester NHS Foundation Trust University Hospitals of Leicester NHS Trust
7. Individual Service User Placement
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Appendix One

National Standards for Nationally Designated Centres: Extra-corporeal Membrane Oxygenation (ECMO) for Adults with Potentially Reversible Severe Respiratory Failure

Purpose of the Document

The purpose of this document is to set out the service standards for the National Extra-corporeal Membrane Oxygenation (ECMO) Service for Adults with Potentially Reversible Severe Respiratory Failure

Aims and overview

NHS England is the national organisation responsible for the commissioning of specialised services and ensuring that these services are safe, effective, patient-centred and of high quality

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.

The ECMO service will be provided within a tertiary level ICU which is able to provide expert advice on the diagnosis and management of severe reversible 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 will retrieve all patients who are accepted for treatment / consideration of ECMO. Centres must be able to provide safe mobile ECMO for patients who are clinically eligible.

Designation of Adult Respiratory ECMO

The national designation of services helps to ensure equitable access to high quality services, particularly when a new intervention becomes available and to ensure concentration of clinical expertise. National services are commissioned through NHS England which ensures that services are provided to the highest standards of quality and meet patient need

The original adult respiratory ECMO service at University Hospitals of Leicester NHS Trust was designated for the period of the CESAR trial (2001-2006). The service continued to be commissioned after this period while awaiting publication of the trial

(Lancet 2009, NIHR HTA programme 2010) and four additional adult centres were commissioned in December 2011.

NHS England will commission ECMO for adults with potentially reversible severe respiratory failure only from nationally designated centres.

Description of Service

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

It is expected that venous-venous ECMO will be undertaken when supporting patients with acute respiratory failure unless there is a clinical indication for venoarterial or Venovenous-arterial (VVA) ECMO.

The adult respiratory ECMO service care pathway encompasses:

- Acceptance of patients referred to the service who fulfil the eligibility criteria for entry to the service
- Specialist retrieval
- Assessment (up to a maximum of 48 hours)
- Treatment: 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

ECMO 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.

Development of standards

The development of the standards for the National Service set out in this document are based on best international practice and the experience gained by providing surge capacity for adult respiratory ECMO during the winters of 2009-10 and 2010-11.

Assessment scores

All services standards are mandatory

Standard 1: Patient centred care

Care for patients will be respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.

Patients, families and carers will have the best possible experience of hospital. Measuring patients' and carers' experience is an integral part of health care regulation and improvement.

Standard	Description
1.1	Patients and carers will be provided with comprehensive information, and appropriate time and support in order that they may make informed decisions about their treatment choices.
1.2	Information will be made available. It will be clear, understandable, culturally sensitive and evidence based – when given verbally, information given will be documented in the patient's medical notes.
1.3	A range of psychological and social support services will be offered to meet the needs of patients and carers. These will be made available at the specialist centre and, when necessary, referral made to local services.
1.4	Patients & carers will have 24-hour access to a member of the ECMO Team for advice, information, support and discussion of specific problems or concerns.
1.5	The views of patients, carers and staff will be regularly and formally sought and the results openly available.
1.6	There will be formal arrangements for addressing complaints and other comments made by patients, carers and staff at other times.
1.7	Staff in the multi-disciplinary ECMO team will have training and be supported in using communication skills. There will be a policy for breaking bad news.
1.8	There will be written guidelines for referral to the ECMO Centre by referring centres agreed with the local critical care network and covering entry criteria, contact details and communication between clinicians and patients.

Standard 2: The Specialist Multi-disciplinary Team including Imaging and Pathology Services

Patients are entitled to high quality safe care which is delivered by an expert workforce, who have specialist knowledge and training and who work collaboratively.

Standard	Description
2.1	**The Specialist Multidisciplinary Team (MDT)** Core members of the Specialist MDT will include: named specialist ECMO clinicians, intensivists, perfusionists, ECMO coordinator and ECMO specialist nurses. In addition, the MDT will include, as required, members from cardiothoracic surgery, physiotherapy, haematology, biochemistry, microbiology, radiology and blood bank. (The composition of the MDT may vary according to the needs of the different aspects of the service e.g. assessment, follow-up, clinico-pathological conferences etc). The attendance and activities of the MDT will be maintained in a register. All MDT members will be invited to take part in clinical governance meetings (held at least quarterly). All medical MDT members will have an annual appraisal.
2.2	**Essential staffing levels:** • Consultant Clinician ECMO Programme Director • Minimum of two associate ECMO consultants (Programme Director and ECMO consultants act as three ECMO consultants, as a minimum, providing 24-hour cover) • One clinical fellow (minimum) or non-consultant grade support, or additional consultant • ECMO Coordinator and deputy • ECMO nurse specialists to provide 1:1 care throughout the course of ECMO. Named additional support personnel from permanent hospital staff 24 hour on-call basis • Clinicians: (cardiology, cardiothoracic surgery, general surgery, vascular surgery, cardiovascular perfusion, anaesthetics, , radiology) • Biomedical engineer • Physiotherapist experienced in intensive care

Standard	Description
	• Perfusion Other clinical staff to be available when needed: • Neurology • Nephrology • OT/physiotherapy • Rehabilitation • Orthopaedics.
2.3	**Laboratory and other Diagnostic Facilities** Each centre will have access to a 24-hour microbiology (including virology), biochemistry and haematology service. Each centre will have access to prompt provision of blood and blood related products. A comprehensive infection control service will available that complies with HSC2001/002 (*The Management and Control of Hospital Infection*) and has evidence of continual improvement to the meet the NHS Executive Controls Assurance Standard in Infection Control.
2.4	All laboratories will be Clinical Pathology Accreditation (CPA) laboratory accredited. All laboratories will meet the requirements of the Health and Safety Good Practice Guidelines and the Royal College of Pathologists Standards. All laboratories will participate in National External Quality Assurance Schemes.
2.5	Each centre will have access to a range of diagnostic imaging 24 hours a day 7 days a week including cardiac catheterisation, angiography, echocardiography, bronchoscopy, ultrasound and CT scanning. They will also have elective access to MR imaging and radionuclide imaging.
2.6	Each centre will have full facilities for comprehensive pulmonary function testing. Quality control audits will be available to the MDT.
2.7	**Patient Care**: Each centre will have named (appropriately trained and experienced) specialist nurse/nurse consultants/clinical assistants/co-ordinators involved in the administration of all aspects of care. These named nurses are members of the MDT. Each centre will have 24 hours a day 7 days a week availability of an ECMO coordinator, consultant and perfusionist in addition to in-