	Yes	No
Policy on the organisations commitment to Health and Safety		
Formal health and safety communication between management and staff		
Systems and procedures in place to ensure employee health and safety at work		
A named person responsible for implementing the organisation's Health and Safety policy		

SECTION F

Workforce

Potential bidders should be prepared to submit further documentary evidence to support their responses in this section at the tender stage or on request. Information provided will be tested robustly at ITT stage.

F.1 Clinical Staffing:

i. Medical

a. Please confirm that the medical workforce cover conforms to the Intensive Care Society and Intercollegiate Board Standards on workforce - including:
Consultant cover: There must be 24 hour cover of the ICU by a named consultant with appropriate experience and level 3 competencies who will not have any other clinical commitments whilst covering the ICU
Junior medical cover: junior medical staff / non-consultant staff assigned to ICU should be full time with no cross cover to other areas. Their shift pattern should be EWTD compliant.

	Yes	**No**
Consultant cover as per standard*	X	
Full time junior medical staff / non-consultant staff cover for ICU (no cross cover)	X	

* *Standards for Consultant Staffing of Intensive Care Units, Intensive Care Society, 2007*

ii. Nursing

Please confirm that the nursing workforce cover conforms to Standards for Nurse Staffing in Critical Care (BACCN) - including

- Senior nurses (band 6 and above) must hold a formal post registration qualification in critical care
- Every patient must have immediate access to a registered nurse with a formal post registration qualification in critical care

	Yes	**No**
Band 6 and above nurses have critical care qualification		
Immediate access to nurse with critical care qualification		

iii. Additional staffing requirements

Please confirm that there are ICU staffing arrangements for the following:

- Dedicated personnel for data collection
- Appropriate access to respiratory physiotherapists 24 hours a day, 7 days a week
- Dietetic input to critical care
- Access to a highly specialised critical care pharmacist

	Yes	No
Dedicated personnel for data collection	X	
Respiratory physiotherapists 24/7	X	
Dietician	X	
Critical care pharmacist	X	

F.2 Recruitment and retention: critical care

i. Please confirm that all the Potential Bidder's Clinical Staff, including doctors, nurses and allied health professionals, have current and appropriate registration with the relevant UK professional and regulatory bodies.

	Yes	No
Comply		

ii. Please confirm that all the Potential Bidder's l Clinical Staff, including doctors, nurses and allied health professionals, meet the Continuing Professional Development (CPD) requirements of their professional and regulatory bodies.

	Yes	No
Comply		

NB: Bidders who are short-listed following the PQQ evaluation will be required at the ITT stage to submit a copy of their proposed Staff Handbook that includes its Human Resources (HR) policies and terms and conditions of employment for staff.

F.3 Compliance

i. Please confirm that the Potential Bidder's workforce policies, strategies, processes and practices comply with all relevant employment legislation applicable in the UK.

	Yes	No
Comply		

ii. The Potential Bidder must confirm compliance of working within the provisions of:

- "Safer Recruitment and Employment - a guide for NHS Employers" (May 2005);
- Standards for Better Health (April 2006); and
- The Code of Practice for International Recruitment of Healthcare Professionals (December 2004). Where the Bidder is not planning to conduct any international recruitment of clinical staff, please state this in the response.

	Yes	No
Comply		

F.4 Training: Critical Care

Please provide details of ongoing education and training for the intensive care medical and nursing workforce with reference to best practice guidelines.
Maximum 2000 words (the use of bullet points is acceptable)

Response
Medical Staff:

Section F: Key guidance documents on workforce

Department of Health

Department of Health, *Adult Critical Care: Specialist Pharmacy Practice*, DH 2005

Department of Health, *Quality Critical Care: Beyond 'Comprehensive Critical Care'*: A report by

the Critical Care Stakeholder Forum, Department of Health / Emergency Care, DH, 2005

Department of Health, *Comprehensive Critical Care: a review of adult critical care services*, DH 2000

Intensive Care Society
Intensive Care Society, *Levels of Critical Care for Adult Patients*, ICS Guidelines, 2009

Intensive Care Society, *Standards for Consultant Staffing of Intensive Care Units*, ICS Guidelines 2007

National Institute for Health and Clinical Excellence
National Institute for Health and Clinical Excellence, *Rehabilitation after Critical Illness*, NICE guideline 89, 2009

National Institute for Health and Clinical Excellence, *Acutely ill patients in hospital: recognition of and response to acute illness in adults in hospital,* NICE guideline 50, 2007

Other
British Association of Critical Care Nurses, *Standards for Nurse Staffing in Critical Care*, BACCN, 2009

Department of Health

Adult Critical Care: Specialist Pharmacy Practice, Department of Health, 2005

Quality Critical Care: Beyond 'Comprehensive Critical Care': A report by the Critical Care Stakeholder Forum, Department of Health / Emergency Care, 2005

Comprehensive critical care: a review of adult critical care services, Department of Health, 2000

Intensive Care Society

Levels of Critical Care for Adult Patients, Intensive Care Society Guidelines, 2009

Standards for Nurse Staffing in Critical Care, BACCN, 2009

Standards for Consultant Staffing of Intensive Care Units, Intensive Care Society Guidelines 2007

National Institute for Health and Clinical Excellence

Rehabilitation after Critical Illness, 2009 (NICE guideline 89), National Institute for Health and Clinical Excellence

Acutely ill patients in hospital: recognition of and response to acute illness in adults in hospital 2007 (NICE guideline no 50), National Institute for Health and Clinical Excellence;

SECTION G

IM&T

Potential bidders should be prepared to submit further documentary evidence to support their responses in this section at the tender stage or on request.

Please confirm that you have experience of working and interfacing with NHS IM&T systems (or equivalents) such as clinical applications, administration systems and business / office applications. This must also include experience of providing support and maintenance to these operating systems.

Experience	**Yes**	**No**
Comply		

G.1 Please confirm that you have experience of using National Programme for IT (NPfIT) infrastructure and services such as N3 and spine services. This should include any experience of managing central data submissions.

Experience	**Yes**	**No**
National Programme for IT (NPfIT) infrastructure		
Services such as N3 and spine services		
Managing central data submissions		

If the Potential Bidder is new or for any other reason has no such experience, please provide evidence or examples of alternative experience to demonstrate that capability for NPfIT.

Response

G.2 Please confirm the Potential Bidder's ability to manage the security, confidentiality and data storage of patient information and in supporting NHS Information Governance requirements (or equivalents) including:

- Any registration under ISO 17799 / 27001 or appropriate information security standards; and
- Policies on security and confidentiality of patient information.

	Yes	**No**
Registration under ISO 17799 / 27001 or appropriate information security standards		
Policies on security and confidentiality of patient information.		
Confirm Information Governance Policy in place		

SECTION H

Local Integration

Potential bidders should be prepared to submit further documentary evidence to support their responses in this section at the tender stage or on request. Information provided will be tested robustly at ITT stage.

H.1 Critical Care Networks

i. Please describe the Potential Bidder's experience of working with their local critical care network The description should include:

a. Details of their local critical care network
b. Information on relationships, especially those other providers in the network
c. Areas of knowledge developed through collaboration

Maximum 2000 words (the use of bullet points is acceptable)

Response

ii. Potential bidders should provide a letter from the network manager/director and clinical lead to confirm that the ICU is;

a. An active member of the network
b. Participates in service improvement
c. Participates in annual audits

	Attached Yes	**Attached No**
Letter provided		

H.2. Geographical coverage:

i. The National ECMO Service will require a number of centres across England, with each centre providing the ECMO service for a defined geographical referral area. The referral areas will need to have a sufficient population to support a minimum activity of 20 ECMO cases a year and where possible be linked to a number of local critical care networks. Potential bidders should indicate whether they currently have links with any

of the listed critical care networks and indicate expressions of interest in providing an ECMO service to other critical care networks in addition to their local network.

	Existing links with network		Expression of Interest	
Critical Care Network	**Yes**	**No**	**Yes**	**No**
Avon & Gloucester				
Birmingham and Black Country				
Central England				
Cheshire & Mersey				
Essex				
Greater Manchester				
Hertfordshire and Bedfordshire				
Kent & Medway				
Lancashire & South Cumbria				
London - North Central				
London - North West				
London -North East				
London -South East				
London -South West				
Mid Trent				
Norfolk, Suffolk & Cambridge				
North of England				
North Trent				
North West Midlands				
North Yorkshire and Humberside				
South Central				
South West Peninsula				
Surrey Wide				
Sussex				
Thames Valley				
Wessex				
West Yorkshire				

ii. Please explain the reasoning for providing an ECMO service to these critical care networks (this should be for each network the potential bidder has indicated an expression of interest) and your rationale for this. Please include information on:

- Details of established links with critical care networks
- How links will be developed with critical care networks where there is not an existing relationship
- How the service can be provided in a timely fashion including reference to retrieval of patients
- Provision of national coverage

Maximum 2000 words (the use of bullet points is acceptable)

Response

All ECMO centres **will be expected** to:

- Accept referrals from an ICU in any area of England if the closest ECMO centre is unable to accept the patient
- Provide surge capacity when requested which potentially will mean taking patients from any of the geographical areas.

iii. Potential bidders should confirm they agree to provide a service to any area of England as necessary to support the delivery of the national ECMO service, and agree to provide surge capacity as required.

	Yes	No
Confirm will accept referrals from ICU in any area of England		
Confirm will provide surge capacity		

SECTION I

Declaration

On completion of the PQQ, please read the declaration below. This page should be signed and returned with your PQQ response.

I certify that the information supplied in the questionnaire is accurate to the best of my knowledge and belief and accords with the basic criteria of eligibility as set out in the National Specialised Commissioning Team's Pre-Qualification Questionnaire and that we have not collaborated with other potential Bidders in the completion of this questionnaire.

I also understand it is a criminal offence, punishable by imprisonment, to give or offer any gift or consideration whatsoever as an inducement or reward to any servant of a public body, therefore I hereby certify and undertake and bind and oblige ourselves and our Connected Persons (as defined below) that we and our Connected Persons have not canvassed or solicited nor will in the future canvass or solicit any officer or employee of the NHS London or the DH or any person acting as an adviser for the NSCT in connection with the selection of Bidders and/or the selection of any submissions, proposals or bids in relation to this project and that our Connected Persons have not nor will so canvass or solicit.

For the purposes of this declaration "Connected Persons" means any person connected with us within the meaning given by Section 839 of the Income and Corporation Taxes Act 1988 and any of the respective directors, officers, employees, solicitors, accountants, bankers or other financial or professional advisers of us and/or of our Connected Persons. Other expressions used in this declaration shall, unless otherwise stated, have the meanings assigned to them in the PQQ issued by National Specialised Commissioning Team.

I agree that we shall be responsible for any failure on the part of Connected Persons to abide by such terms to the same extent as if such failure had been our own action or omission.

I hereby declare that I am authorised by the under mentioned potential Bidder to supply the information given above and that, at the date of signing, the information given is a true and accurate record.

Signed _____

Name _____

Position _____

Entity _____

Date _____

An authorised signatory, in his / her own name, on behalf of the potential Bidder and **each** Relevant Organisations, must sign a copy of this declaration.

SECTION J

INFORMATION ON ADVISERS

This section must be completed by the potential Bidder in respect of each Relevant Organisation and their advisers.

L1 Details of Organisations / Advisers

Registered Name:	
Current Trading Name:	
Previous Trading Names (if different):	
Registered Address:	
Telephone:	
Fax:	
E-mail:	
Registered No:	
Year of Registration:	
Country of Registration:	

III. 考察

落合亮一

本研究の目的は，急性呼吸不全 ARDS の重症例の予後を改善するシステムを構築することにある．そこで，まず ARDS の現在の位置付けと我が国における歴史と問題点を整理する．

ARDS の標準的治療方針とその選択肢

ARDS は，1969 年に急性発症の呼吸不全として疾患概念が紹介されて以来，50 年近くが経過しているが，その予後は極めて悪く改善の兆しがみられずにきた(1)．このため，2012 年に開かれた欧米の専門家によるコンセンサス会議の結果，『ベルリン定義』として，現在の標準的治療方針が示されている(2)．ベルリン定義では，酸素化の障害レベルによって ARDS の重症度を軽症，中等症，重症と分類している．人工呼吸管理以外の治療選択肢として，筋弛緩薬の使用，腹臥位管理の導入，高頻度振動換気の導入，体外式二酸化炭素除去装置の使用，そして ECMO の導入が挙げられている (3)．こうした新しい治療方針が今後，どのような予後の改善を来すのか，大変に期待されるものである．実際，1994 年に開かれた欧米専門家によるコンセンサス会議では，ECMO をはじめとする治療選択肢は，触れられていなかったことからも，新たな展開があったことが窺い知れる(4)．

ECMO の普及とその背景

最重症例に適応があるとする ECMO であるが，その歴史は決して容易なものではなかった．体外循環を用いて心配補助を行うというアイディアは 1930 年代まで遡るが，その後，様々な技術革新を経て，現実化したのはシリコン膜が開発されてからである (5-7)．しかし，その生存率は極めて低かった．

2009 年に H1N1 インフルエンザが世界的に大流行し，重症肺炎が多く報告されたが，その際に，ECMO を用いて救命しえたとする報告が各国から挙がり，ARDS の治療に ECMO という選択肢のあることが極めて注目を浴びる結果となった (8)．実際，生存率第 1 位はスウェーデンで 92%，2 位は英国で 73%，3 位はオーストラリア・ニュージーランドで 71% と極めて高い数字が報告されている．一方で，我が国において H1N1 インフルエンザ肺炎に ECMO を使用した症例登録データからわかるのは，生存率が 36% と極めて低かったということである (9)．この極めて低い生存率は，何によるものであろうか．

我が国の現状と問題点

我が国における ECMO は，開心術時の人工心肺以外には，心肺停止症例の蘇生に用いられてきたという歴史がある．実際，蘇生に用いる際には，短時間で準備が可能であること，セットアップが簡便であること，短期間の使用であること，などを特徴とした ECMO 装置が適しているが，一方で呼吸不全に用いる際には使用期間が極めて長い特徴があり，専用の装置を必要とする点で我が国の装置と異なっていた．また，循環不全に焦点を当てた治療に邁進してきたため，呼吸不全への対応は経験もなく，教育のための教材も装置や設備もなかったことが，我が国における低迷した生存率の原因であったものと考えられる．

日本呼吸療法医学会で調査を行った際に，我が国には約 1,500 台の ECMO 装置が約 1,000 の施設で用いられている．心肺蘇生のために各救命センターや救急外来に装備された結果と考えられるが，1 施設あたりの患者密度が極端に低い結果を生じている〔厚労科研・竹田班 (H25-特別-指定-024)〕．つまり．どの施設も ARDS に対して ECMO を導入した経験は，極めて稀なものであると考えられる．

例えば，ECMO による呼吸不全の治療成績が良い英国では，全国に５つのセンターがあるのみで，患者集積は極めて高いことがわかる．実際，ECMO 治療の成績について，ELSO が症例登録のデータを解析した結

果，患者密度と治療成績は密接な関係があり，治療成績を向上させるためには，センター化が不可欠であることを示している（10）.

我が国における ECMO を用いた呼吸不全の治療を考える際に，こうした現実とどう対処していくべきかを考える必要がある．つまり，

- ARDS に対する ECMO 治療の教育環境を整備する必要性
  - 教育に必要な世界標準の教科書の発行
  - 実践に即したハンズオンセミナーの開講
- 治療成績の評価
  - 患者登録システムの開発
  - 施設認定と登録された症例の評価法の調査

我が国においては，ARDS に対する ECMO 治療について，どの施設でも十分な経験や診療環境が整っていない．こうした状況で，英国にみられるようなセンター化は困難である．教育環境を提供しながら，その成果を登録された症例の治療成績から客観的に評価する環境を創る必要があり，上記４点を本研究のゴールとした．その結果，本研究のゴールは達成されたものと考える．

今後は，このシステムを利用し，徹底的な教育の導入と，施設ごとの診療内容の評価が可能となり，数年後には ARDS に対する ECMO 治療のセンター化が可能になるものと期待される．

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IV. 結論

落合亮一

- 急性呼吸不全 ARDS の治療にあたって，重症例は未だに治療成績が芳しくなく，死亡率が 30% を超えているため，新しいアプローチが求められてきた.
- その選択肢には，腹臥位換気や高頻度振動換気などの古典的なアプローチも有用と考えられているが，登録された症例のデータからは，ECMO を用いた治療が有用であることが確認されている.
- 循環不全時に遭遇する蘇生に対して用いる，我が国独自の PCPS (percutaneous cardiopulmonary support) の臨床的意義を明らかにし，急性呼吸不全に対するアプローチを確立すべきである.
- 将来的に ARDS に対して有効な治療法を提供できる施設として，登録された施設からセンター化を行うシステムを考える必要がある.

V. 研究成果

A. 刊行物『ECMO 4th Edition〈日本語版〉』

次ページ以降に掲載した.

B. 健康危険情報

なし.

C. 研究発表

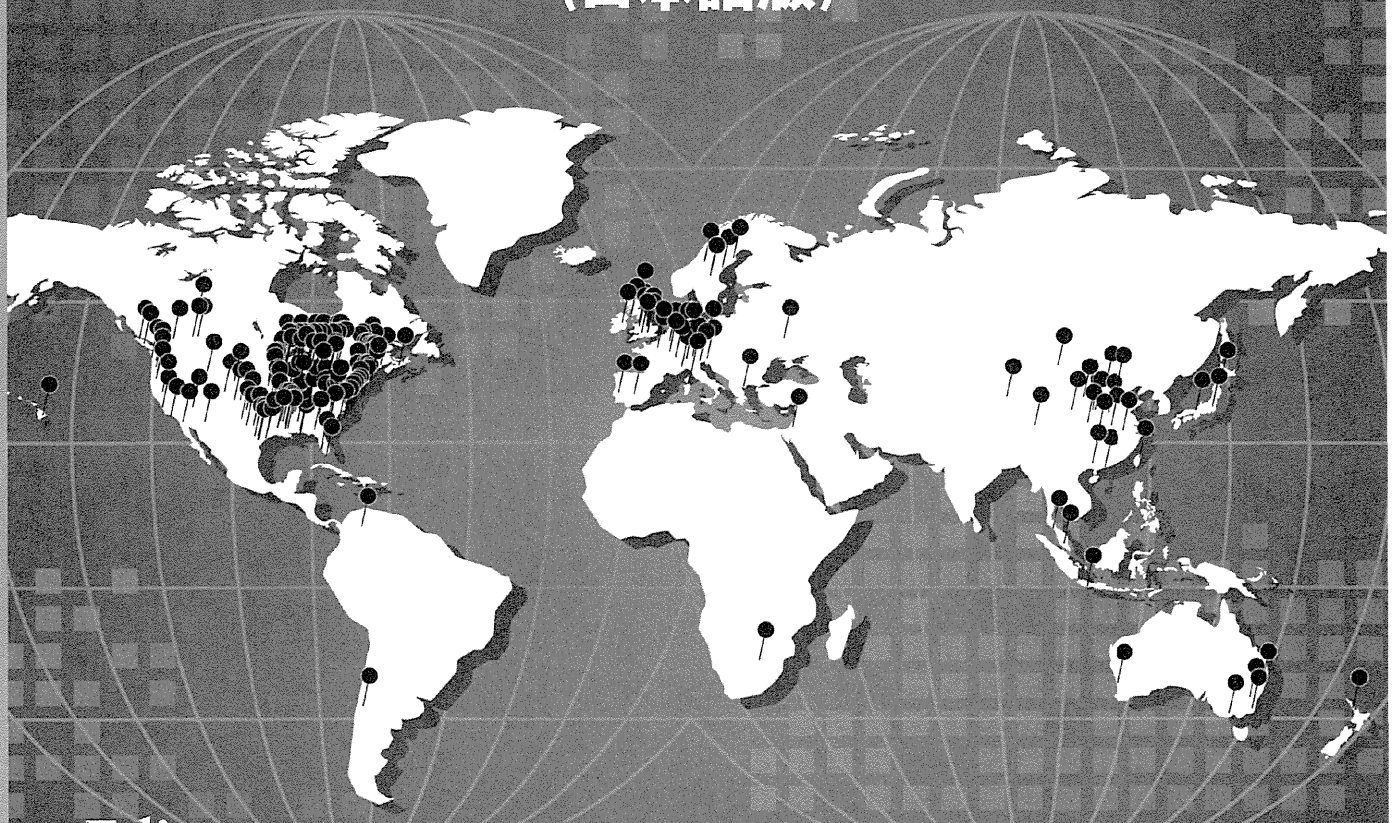
なし.

D. 知的財産権の出願・登録状況

なし.

ECMO 4th Edition 〈日本語版〉

ECMO
Extracorporeal Cardiopulmonary Support in Critical Care
4th Edition
〈日本語版〉



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EXTRACORPOREAL LIFE SUPPORT ORGANIZATION
Established 1989

ECMO

Extracorporeal Cardiopulmonary Support in Critical Care

4th Edition

〈日本語版〉

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