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:	

５）ECMO のエビデンスの確認

最重症の呼吸不全 (ARDS) 症例について，治療指針としての ECMO は臨床研究におけるエビデンスを加えて，きちんと説明することが必要。

Evidence: Severe Respiratory Failure & ECMO

Nicholas Barrett
Consultant in Critical Care
Lead for Severe Respiratory Failure

Guy's and St Thomas' NHS
NHS Foundation Trust

KING'S HEALTH PARTNERS

ARDS

- ARDS is a syndrome of inflammation and increased permeability associated with a constellation of clinical, radiologic, and physiologic abnormalities unexplained by elevations in left atrial or pulmonary capillary pressure.
- Caused by a variety of insults – direct or indirect

Guy's and St Thomas' NHS
NHS Foundation Trust

Acute diffuse inflammatory injury

- Loss of aerated lung tissue
- Increased vascular permeability

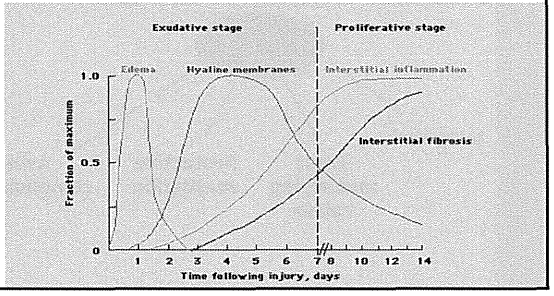
↓

- Increased alveolar dead space
- Increased pulmonary shunt
- Decreased lung compliance
- Increased lung tissue oedema

Bilateral infiltrate ⇔ Hypoxaemia/hypercapnoea

Guy's and St Thomas' NHS
NHS Foundation Trust

ARDS – Time Course



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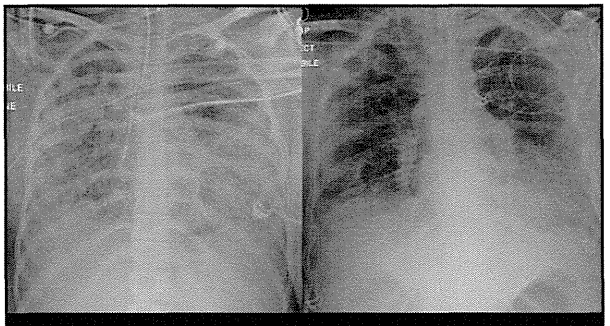
NHS Foundation Trust

ARDS

- AECC Definition
  - PaO2/FiO2 <26.5kPa (200mmHg)
  - PCWP <18mmHg
  - Bilateral infiltrate
  - Acute onset

BUT



FiO2 1.0, PaO2 4, P/F 4,
TV 150mL, Pplat 30, PEEP 15

FiO2 0.5, PaO2 9, P/F 18
TV 400mL, Pplat 20, PEEP 8

Guy's and St Thomas' NHS
NHS Foundation Trust

PaO2/FiO2 <13.3kPa (<100mmHg)

- Incidence approx 20-30%
- Observational series
  - ARDSNet database 70% mortality
  - ICNARC 62% mortality
- Pooled from 4 recent ARDSNet RCTs
  - 40% vs 25% approx
  - Highest mortality IF PaO2/FiO2 <13.3 kPa AND PEEP >10

The value of positive end-expiratory pressure and Fio_2 criteria in the definition of the acute respiratory distress syndrome*

Marlin Ribos, MD; Elizabeth Smoot, MS; Kathleen D. Liu, MD; B. Taylor Thompson, MD; William Checkley, MD, PhD; Roy G. Brower, MD, for the National Institutes of Health Acute Respiratory Distress Syndrome Network Investigators

Guy's and St Thomas' NHS
NHS Foundation Trust

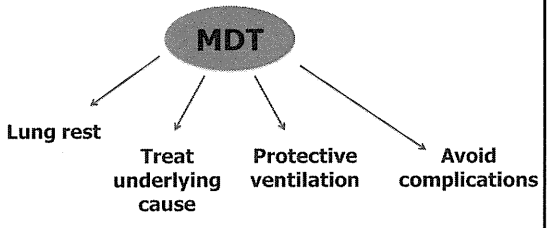
Berlin Definition

	Acute Respiratory Distress Syndrome
Timing	Within 1 week of a known clinical insult or new or worsening respiratory symptoms
Chest imaging[a]	Bilateral opacities—not fully explained by effusions, lobar/lung collapse, or nodules
Origin of edema	Respiratory failure not fully explained by cardiac failure or fluid overload Need objective assessment (eg, echocardiography) to exclude hydrostatic edema if no risk factor present
Oxygenation[b]	
Mild	200 mm Hg < Pao_2/Fio_2 ≤ 300 mm Hg with PEEP or CPAP ≥5 cm H_2O[c]
Moderate	100 mm Hg < Pao_2/Fio_2 ≤ 200 mm Hg with PEEP ≥5 cm H_2O
Severe	Pao_2/Fio_2 ≤ 100 mm Hg with PEEP ≥5 cm H_2O

JAMA (2012)

Guy's and St Thomas' NHS
NHS Foundation Trust

Principles of Management



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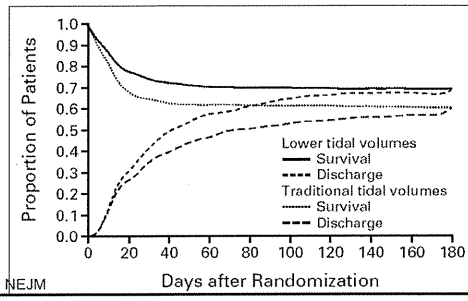
Conventional Management



ARDSNET(1999) NEJM

Fluid

Outcome	Conservative Strategy	Liberal Strategy	P Value
Death at 60 days (%)	25.5	28.4	0.30
Ventilator-free days from day 1 to day 28†	14.6±0.5	12.1±0.5	<0.001
ICU-free days‡			
Days 1 to 7	0.9±0.1	0.6±0.1	<0.001
Days 1 to 28	13.4±0.4	11.2±0.4	<0.001
Organ-failure–free days†‡			
Days 1 to 7			
Cardiovascular failure	3.9±0.1	4.2±0.1	0.04
CNS failure	3.4±0.2	2.9±0.2	0.02
Renal failure	5.5±0.1	5.6±0.1	0.45
Hepatic failure	5.7±0.1	5.5±0.1	0.12
Coagulation abnormalities	5.6±0.1	5.4±0.1	0.23
Days 1 to 28			
Cardiovascular failure	19.0±0.5	19.1±0.4	0.85
CNS failure	18.8±0.5	17.2±0.5	0.03
Renal failure	21.5±0.5	21.2±0.5	0.59
Hepatic failure	22.0±0.4	21.2±0.5	0.18
Coagulation abnormalities	22.0±0.4	21.5±0.4	0.37
Dialysis to day 60			
Patients (%)	10	14	0.06
Days	11.0±1.7	10.9±1.4	0.96

ARDSNET (2006) NEJM

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NHS Foundation Trust

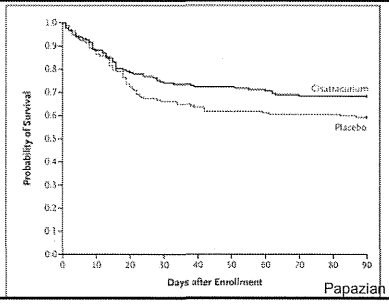
PEEP

Outcome	Lower-PEEP Group	Higher-PEEP Group	P Value
Death before discharge home (%)†			
Unadjusted	24.9	27.5	0.48
Adjusted for differences in baseline covariates	27.5	25.1	0.47
Breathing without assistance by day 28 (%)	72.8	72.3	0.89
No. of ventilator-free days from day 1 to day 28‡	14.5±10.4	13.8±10.6	0.50
No. of days not spent in intensive care unit from day 1 to day 28	12.2±10.4	12.3±10.3	0.83
Barotrauma (%)§	10	11	0.51
No. of days without failure of circulatory, coagulation, hepatic, and renal organs from day 1 to day 28	16±11	16±11	0.82

ARDSNET (2004) NEJM

Guy's and St Thomas' NHS
NHS Foundation Trust

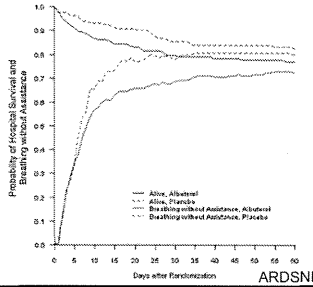
Neuromuscular blockade



Papazian (2010) NEJM

Guy's and St Thomas' NHS
NHS Foundation Trust

Inhaled β2 agonists



ARDSNET (2011) AJRCCM

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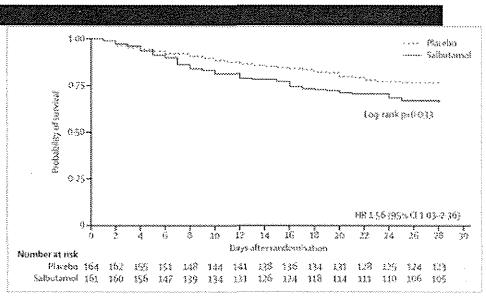
IV β2 agonists



Smith (2012) Lancet

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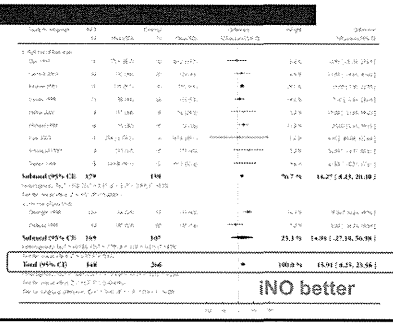
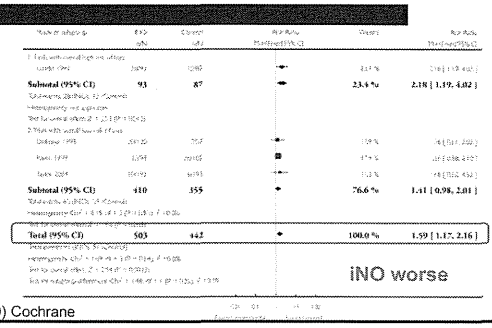
iNO & oxygenation



Afshari (2010) Cochrane

Guy's and St Thomas' NHS
NHS Foundation Trust

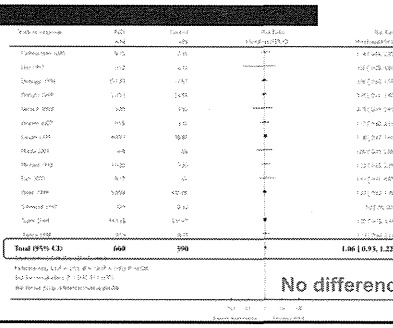
iNO & renal failure



Afshari (2010) Cochrane

Guy's and St Thomas' NHS
NHS Foundation Trust

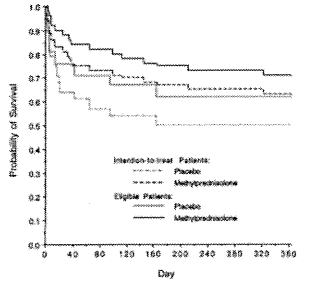
iNO & mortality



Afshari (2010) Cochrane

Guy's and St Thomas' NHS
NHS Foundation Trust

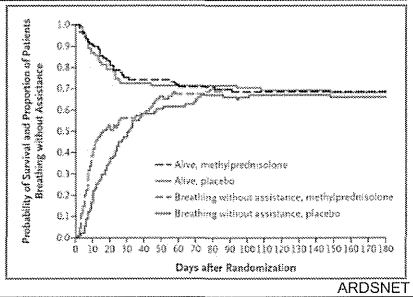
Early steroids, severe ARDS



Meduri (2007) Chest

Guy's and St Thomas' NHS
NHS Foundation Trust

Late steroids & outcome



ARDSNET (2006) NEJM

Guy's and St Thomas' NHS
NHS Foundation Trust

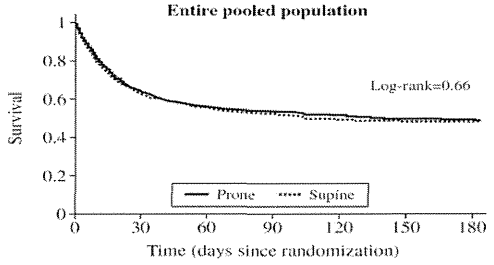
Procollagen – predictor of outcome?

Variable	Placebo (N=91)	Methylprednisolone (N=89)	P Value
60-Day mortality (%)	28.6	29.2	1.0
60-Day mortality according to time from ARDS onset			
7–13 Days (%)	36	27	0.26
No. of patients	66	66	
>14 Days (%)†	8	35	0.02
No. of patients	25	23	
60-Day mortality according to baseline BAL procollagen peptide type III level			
< Median (%)	9	35	0.03
No. of patients	23	23	
> Median (%)†	19	4	0.10
No. of patients	21	24	

ARDSNET (2006) NEJM

Guy's and St Thomas' NHS
NHS Foundation Trust

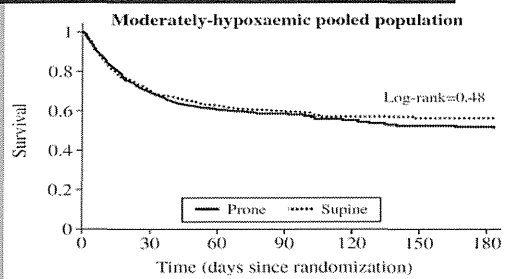
Prone-positioning meta-analysis



Gattinoni 2010, *Minerva Anestesiol*

Guy's and St Thomas' NHS
NHS Foundation Trust

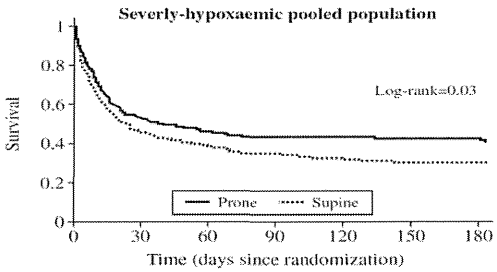
Prone-positioning meta-analysis



Gattinoni 2010, *Minerva Anestesiol*

Guy's and St Thomas' NHS
NHS Foundation Trust

Prone-positioning meta-analysis



Gattinoni 2010, *Minerva Anestesiol*

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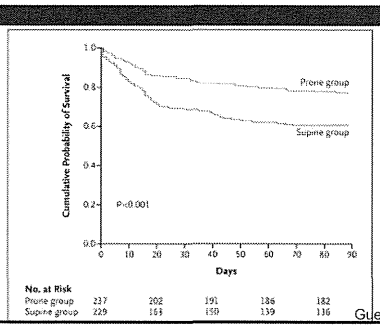
NHS Foundation Trust

Prone position > 16 hours, PF <150mmHg



Guerin, *NEJM* 2013

Guy's and St Thomas' NHS
NHS Foundation Trust

Uncontrolled studies with HFOV

Study	Design	N	Comment	Mortality (%)
Fort 1997	Prospective	17		53
Claridge 1999	Prospective	5	Trauma	20
Metha 2001	Prospective	24		66
Carlotto 2001	Retrospective	6	Burn	83 3
Andersen 2002	Retrospective	16		31
Metha 2003	Prospective	23		61
David 2003	Prospective	42		43
Metha 2004	Retrospective	156		61
Ferguson 2005	Prospective	25		44
Pachl 2006	Prospective	30		46
Finkleman 2006	Retrospective	14		57

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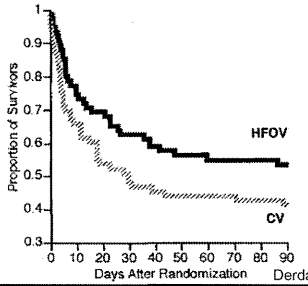
NHS Foundation Trust

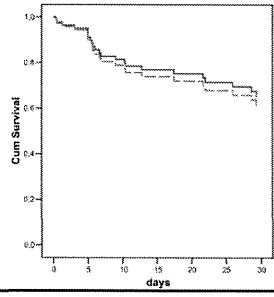
HFOV



Derdak (2002) AJRCCM

Guy's and St Thomas' NHS
NHS Foundation Trust

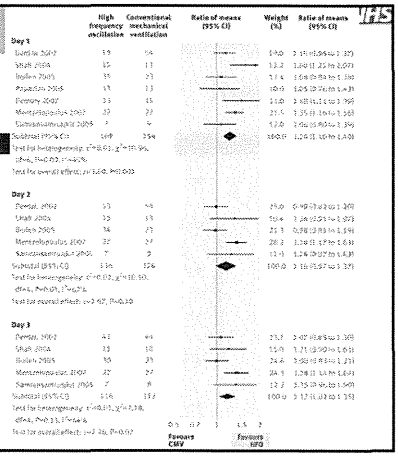
HFOV - RCT



Bollen (2005) Crit Care

Guy's and St Thomas' NHS

HFOV O2



Sud et al, BMJ 2010

Guy's and St Thomas' NHS
NHS Foundation Trust

HFOV - mortality

	High frequency oscillation	Conventional mechanical ventilation	Risk ratio (95% CI)	Weight (%)	Risk ratio (95% CI)
Arnold 1994	10/29	12/29		13.0	0.83 (0.43 to 1.62)
Derdak 2002	28/75	38/73		42.6	0.72 (0.50 to 1.03)
Shah 2004	6/15	6/13		7.9	0.87 (0.37 to 2.04)
Bollen 2005	16/37	8/24		12.5	1.30 (0.66 to 2.55)
Mentzelopoulos 2007	11/27	18/27		20.6	0.61 (0.36 to 1.04)
Samransamruajkit 2005	2/6	5/10		3.4	0.67 (0.18 to 2.42)
Total (95% CI)	73/189	87/176		100.0	0.72 (0.61 to 0.98)

Test for heterogeneity: χ^2=0.00, χ^2=3.26, df=5, P=0.64, I^2=0%
Test for overall effect: z=2.12, P=0.03

0.1 0.2 0.5 1 2 5 10
Favours HFO
Favours CMV

Sud et al, BMJ 2010

Guy's and St Thomas' NHS
NHS Foundation Trust

OSCILLATE & OSCAR

- OSCILLATE
  - PF < 200mmHg (26kPa), duration <14 days
  - Single recruitment (40cmH2O for 40 seconds)
  - Commence HFO at 30cmH2O, up to 38cmH2O
  - Wean per O2/CO2 targets
- OSCAR
  - PF < 200mmHg (26kPa), duration <7 days
  - No recruitment
  - Commence HFO at 5cmH2O above current mean airway pressure, up to 50cmH2O in 5cmH2O increments
  - Wean per O2/CO2 targets

Guy's and St Thomas' NHS
NHS Foundation Trust

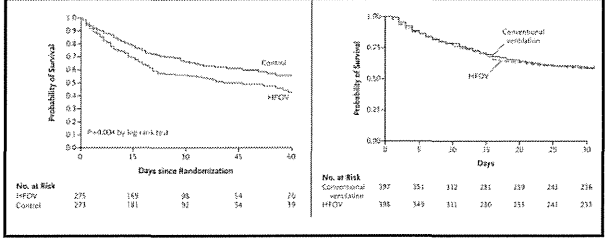
OSCILLATE

Component Variable	HFOV	Control Ventilation
Ventilator mode	High-frequency oscillatory ventilation	Pressure control
Tidal volume target (ml/kg of predicted body weight)	NA	6
Tidal volume range (ml/kg of predicted body weight)	NA	4–8
Plateau airway pressure (cm of water)	NA	≤35
Positive end-expiratory pressure (cm of water)	NA	Adjusted according to oxygenation†
Mean airway pressure (cm of water)	Adjusted according to oxygenation†	Measured but not adjusted
Respiratory frequency	3–12 Hz	≤35 breaths/min
Pressure amplitude target (cm of water)	90	NA
Partial pressure of arterial oxygen (mm Hg)	55–80	55–80
Oxygen saturation by pulse oximetry (%)	88–93	88–93
Arterial blood pH	7.25–7.35	7.30–7.45
Ratio of inspiratory-to-expiratory time	1:2	1:1–1:3
Recruitment maneuvers	Yes	Yes

Guy's and St Thomas' NHS
NHS Foundation Trust

HFOV - RCTs

OSCILLATE **OSCAR**



Guy's and St Thomas' NHS
NHS Foundation Trust

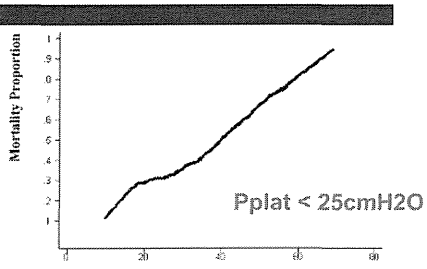
OSCAR – Protective ventilation?

Table 2. Ventilatory Variables during the First 3 Study Days.*

Variable	Day 1		Day 2		Day 3	
	HFOV	Conventional Ventilation	HFOV	Conventional Ventilation	HFOV	Conventional Ventilation
No. of patients	370	392	326	374	240	348
Mean airway pressure (HFOV) or plateau pressure (conventional ventilation) — cm of water	28.9±6.2	30.9±11.0	25.3±5.3	29.3±10.7	23.1±5.4	28.5±13.2
Total respiratory frequency — Hz (HFOV) or breaths/min (conventional ventilation)	7.8±1.3	21.7±8.4	7.5±1.8	22.7±9.0	7.2±1.8	23.3±8.2
Cycle volume (HFOV) or tidal volume (conventional ventilation) — ml (HFOV) or ml/kg of ideal body weight (conventional ventilation)	213±72	8.1±2.9	228±75	8.2±2.5	240±75	8.6±3.0
Positive end-expiratory pressure — cm of water (conventional ventilation only)	NA	11.4±3.6	NA	11.0±3.6	NA	10.5±3.7
$Pa_{O_2}/F_{I_{O_2}}$ ratio — mm Hg	192±77	154±63	212±69	163±66	217±69	166±63
Pa_{CO_2} — mm Hg	55±17	50±19	56±16	49±13	56±17	48±13
Arterial pH	7.30±0.10	7.35±0.10	7.32±0.09	7.37±0.10	7.34±0.10	7.39±0.09
Medication use — no. (%)†						
Neuromuscular-blocking agent	209 (52.5)	165 (41.6)	147 (36.9)	115 (29.0)	110 (27.6)	77 (19.4)
Vasoactive or inotropic agent	173 (43.5)	177 (44.6)	158 (40.0)	146 (36.8)	126 (31.7)	112 (28.2)
Sedative agent	390 (98.0)	385 (97.7)	371 (93.2)	363 (91.4)	341 (85.7)	335 (84.4)

Guy's and St Thomas' NHS
NHS Foundation Trust

Optimal protective ventilation?



Hager, 2005, AJRCCM

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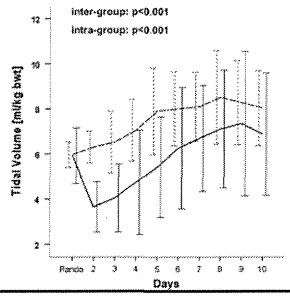
Xtravent



Bein (2013) ICM

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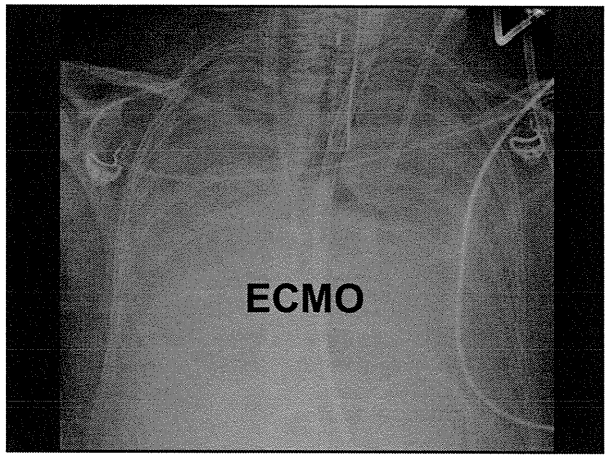
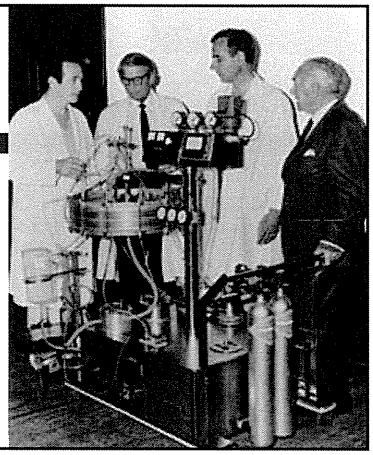
Xtravent

	Subgroup: PaO_2/FIO_2 <150		
	$avECCO_2$-R	Control	*p*
Ventilator-free-days-28	11.3 ± 7.5	5.0 ± 6.3	0.033
Ventilator-free-days-60	40.9 ± 12.8	28.2 ± 16.4	0.033
Non-pulmonary organ failure free days-60	24.1 ± 7.5	29.0 ± 17.7	0.428
Lung injury score on day 10	2.3 ± 0.8	2.2 ± 0.5	0.601
Length of stay in hospital (days)	42.0 ± 16.6	40.3 ± 15.7	0.815
Length of stay in ICU (days)	25.9 ± 13.1	31.0 ± 12.7	0.258
In-hospital mortality	1/21 (4.8 %)	1/10 (10 %)	0.563

Bein (2013) ICM



History



Bramson membrane lung circa 1960s

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ECMO - history

- Hill JD et al. *Circulation* 1968: (S2); 139-145
  26yrs female; b/l pneumonia
  26hr veno-venous perfusion
  RIP 48hrs post 'bypass'
- Hill JD et al. *NEJM* 1972: **286**; 629-634
  24yrs male; blunt trauma with 'shock lung'
  75hrs veno-venous perfusion
  Patient recovered

"End stage shock lung may be reversible if the patient receives adequate gas exchange through partial extra corporeal circulation with an appropriate membrane lung"

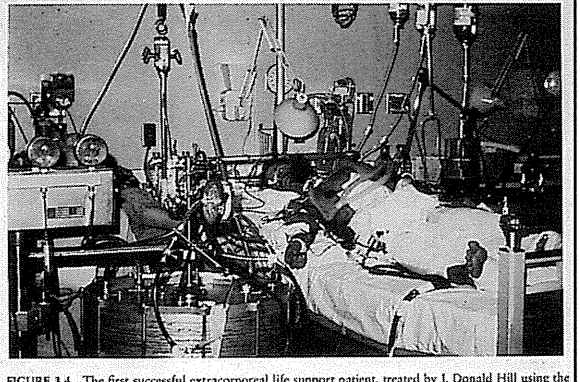

FIGURE 3.4 The first successful extracorporeal life support patient, treated by J. Donald Hill using the Bramson oxygenator (foreground), Santa Barbara, 1971.

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Early RCTs

- NIH Adult ECMO Trial
  - Survival < 10% in both arms
- PCIRV vs ECCO2R
  (*AJRCCM*,1994;149:295-305)
  - 33% survival in 21 patients ECCO2R + LFPPV
  - 42% survival in 19 patients PCIRV

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Criticisims

- Inexperienced centres
- High levels of positive pressure ventilation used – before and during ECMO
- High levels of anticoagulation
- High frequency of bleeding complications
- >7 days of conventional therapy prior to ECMO

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Technical advances

- Membrane oxygenators
  - Polymethylpentene
- Heparin bonded tubing
- Pumps
  - Centrifugal
- Miniaturisation

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ECMO: a re-developing trend

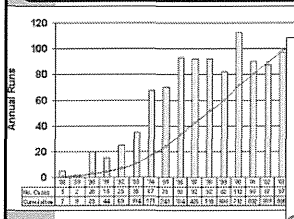

Table 2. Total Numbers of ECLS Cases Reported by the ELSO Registry International Summary, July 2004

	Total Cases	Survive to Discharge or Transfer: Number	%
Neonatal			
Respiratory	19,661	14,681	77
Cardiac	2,215	841	38
ECPR	151	65	43
Pediatric			
Respiratory	2,762	1,536	56
Cardiac	2,139	1,256	43
ECPR	280	111	39
Adult			
Respiratory	972	516	53
Cardiac	474	156	33
ECPR	132	50	38
Total	28,986	19,211	66

Conrad (2005) ASAIO

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ECMO - CESAR

- RCT
- Primary hypothesis:
  - Consideration for ECMO will increase rate of survival without severe disability
- Allocated to:
  - consideration for treatment by ECMO (retrieved to Glenfield)
  - conventional management (remained in referring hospital)

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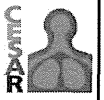
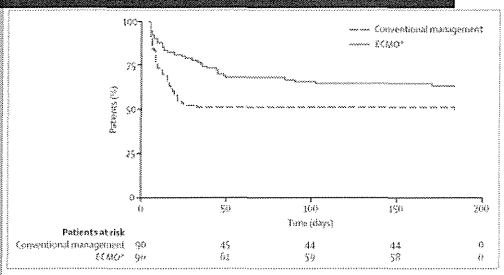
CESAR – Survival





Peek (2009) Lancet

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CESAR - criticisms

	ECMO group (n=90)*	Conventional management group (n=90)	
Treatment by other management			
Missing all data	2 (2%)	0	NA
High-frequency oscillation or jet ventilation	6 (7%)	13 (14%)	0·21
Nitric oxide	9 (10%)	6 (7%)	0·60
Prone position	32 (4%)	38 (42%)	0·58
Steroids	76 (84%)	58 (64%)	0·001
MARS	15 (17%)	0	<0·0001
Continuous venovenous haemofiltration	72 (80%)	76 (84%)	0·61
Treatment by low-volume low-pressure ventilation strategy at any time	84 (93%)	63 (70%)	<0·0001
Time under strategy (days)	23·9 (20·4)	15·0 (21·1)	<0·0001

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6 month outcomes

	ECMO group (n=90)*	Conventional management group (n=90)
Lung capacity		
FEV_1 (L; percent of predicted value)	2·6 (0·1); 74·9% (2·0)	2·5 (0·1); 72·9% (3·3)
FVC (L; percent of predicted value)	3·3 (0·1); 79·6% (2·4)	3·2 (0·2); 79·9% (3·6)
FER (L; percent of predicted value)	81·9 (1·5); 101·0% (1·7)	81·6 (2·2); 100·7% (2·5)
PEFR (L; percent of predicted value)	370·7 (16·1); 74·5% (2·4)	364·3 (20·5); 75·1% (3·6)
Data missing	3 (3%)	2 (2%)
Problems with usual activities		
None	21 (23%)	10 (11%)
Some	25 (28%)	19 (21%)
Unable	6 (7%)	4 (4%)
Pain or discomfort		
None	23 (26%)	13 (14%)
Moderate	22 (24%)	18 (20%)
Extreme	7 (8%)	2 (2%)
Anxiety or depression		
None	23 (25%)	21 (23%)
Moderate	26 (29%)	9 (10%)
Extreme	3 (3%)	3 (3%)

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ARDS 5 year outcomes - respiratory

Clinical Outcomes	At 1 Year (N = 83)	At 2 Years (N = 69)	At 3 Years (N = 71)	At 4 Years (N = 63)	At 5 Years (N = 64)
Pulmonary function — % of predicted†					
Forced vital capacity					
Median	85	86	76	84	84
Interquartile range	71–98	71–100	67–98	70–100	72–101
Forced expiratory volume in 1 sec					
Median	86	87	79	85	83
Interquartile range	74–100	75–99	66–97	68–98	69–98
Total lung capacity‡					
Median	95	94	93	92	94
Interquartile range	81–103	84–108	78–107	79–104	78–105
Residual volume‡					
Median	105	96	101	96	96
Interquartile range	90–116	78–118	80–116	80–110	73–108
Carbon monoxide diffusion capacity‡					
Median	72	78	77	82	80
Interquartile range	61–85	65–89	63–93	68–94	70–86

Herridge (2011) NEJM

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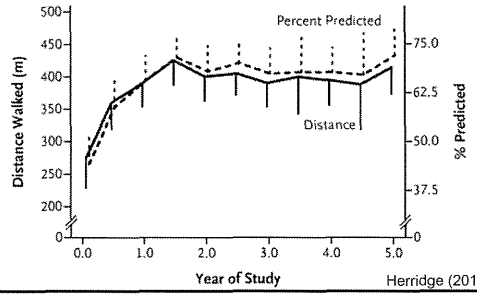
ARDS 5 year outcomes - walk test



Herridge (2011) NEJM

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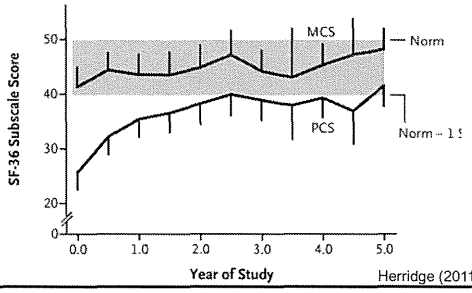
ARDS 5 year outcomes - QOL



Herridge (2011) NEJM

６） 評価基準

ECMO センターとなった施設に対しては、継続的な評価を行う必要がある。

Service Specification – Adult Critical Care ECMO for Respiratory Failure

What is Critical Care?

'Critical Care' includes care delivered in 'Intensive Care (ICU), Intensive Therapy (ITU) and High Dependency care (HDU) units. Critical Care is needed if a patient requires specialist monitoring, treatment or attention for example, after complex surgery, a life threatening illness or a life threatening injury. For more information, see the separate Service Specification for Adult Critical Care services.[1]

What is ECMO?

Extracorporeal Membrane Oxygenation (or ECMO) is highly specialised support given in some intensive care units to critically ill patients who have severe respiratory or lung failure. It involves giving oxygen to the blood outside of the body so that other organs that get oxygen from the blood may continue to work. ECMO not, in itself, a treatment for respiratory failure but can replace the function of the lungs so that treatments may be started or continued and give them a chance to heal and recover. The respiratory failure may be caused by a serious lung or breathing disease or injury or may be a consequence of another clinical condition such as cardiac failure. More details regarding ECMO treatment may be found at the website of the National Institute of Health and Clinical Excellence[2] It is important to realise that ECMO is not a suitable for all patients with severe lung failure. ECMO is a very specialised service requiring highly skilled clinicians and only certain, designated, hospitals are able to provide the service. These hospitals provide a comprehensive national advice and support service that is accessible to patients whenever it may be needed.

This Specification only applies to adults (i.e. patients aged over 16 years). ECMO is also provided for children and babies. Separate specifications are being developed covering these patients.

The Service Specification

This Service Specification describes the standards that are to be delivered to patients requiring ECMO within an ICU at one of the specialist designated hospitals. In addition to ECMO, these ICUs will also be expected to be able to provide the full range of other treatments and interventions that are normally available in all ICUs. This means that ICUs covered by this Specification must also meet all the conditions described in the separate service specification for all adult critical care services mentioned above.

The Service Specification describes the minimum standards required of an ICU that is providing and ECMO service. It complies with the principles of care as set out in the NHS Outcomes Framework[3]. Those with particular relevance to this service are:

- to enhance patients' experience of treatment;
- to provide a safe environment in which they are treated;

[1] Service Specification – Adult Critical Care Services. NHS England ?
[2] National Institute of Health and Clinical Excellence: www.nice.org.uk/IPG391/publicinfo
[3] NHS Outcomes Framework – Domains and Indicators. DH. London 2010

- to protect patients from avoidable harm;
- to help recovery from episodes of ill health or injury; and
- to prevent premature death.

The Specification is built around a number of key principles that, together, form the components of a high quality ECMO service.

What do these principles mean for a patient who has severe lung failure?

Equality of Access to the Service:

It is a fundamental principle that ECMO will be available to all patients who will benefit from it, how their care is commissioned or how it is paid for. Although this Specification applies to NHS ECMO providers in England, the ECMO Service has close links with hospitals in other UK countries and, indeed, elsewhere in Europe.

Normally patients will be first admitted to an Intensive Care Unit within a general hospital where the seriousness of their illness will be assessed. The ECMO service provider will be available to give advice and support to the patient's hospital 24 hours a day for 365 days a year. If it is considered that the patient's condition may benefit from ECMO, the ECMO provider will make a detailed specialist assessment. If this confirms that the patient's condition can be helped by ECMO and they are otherwise suitable for the support (for instance, that they do not have some other complicating condition that may make ECMO unsuitable or particularly hazardous), the ECMO centre will accept the patient and arrange for a specialist retrieval team to help transport the patient to one of the specialist hospitals. This may be done by land or air transport and although the aim will be to transport the patient to the nearest specialist centre, this may not be always be possible particularly during periods of increased work such as during a virulent influenza epidemic. It is a condition of the Specification that ECMO providers must have plans to anticipate and manage seasonal variations and unexpected surges in demand for ECMO. This assessment and retrieval service must also be available all day on every day of the year.

The Care Provided

If you are a patient admitted to a specialist ECMO ICU in England, you will know that the Centre into which you have been admitted will meet the standards agreed with NHS England for designated ECMO centres.[4] You and your family members or carers will be provided with comprehensive information regarding your condition and the procedures you are likely to be given along with possible consequences, the possible course that the care may take and likely outcomes both for you as a patient and your family. A range of psychological and social service support services will be offered to you and your family either at the specialist centre or through local services in your community or your local hospital. You and your family members will have 24 hour access to a member of the ECMO team for advice, information or to discuss specific problems or concerns.

It is a requirement of the Specification that the care you receive will meet the latest evidence based guidelines and procedures. The care provided in the ICU will be

[4]National Standards for Nationally Designated Centres: Extra-corporeal Membrane Oxygenation (ECMO) for Adults with Potentially Reversible Severe Respiratory Failure. NHS England. London. ?

regularly monitored to ensure that compliance with these guidelines and procedures is being maintained.

The Centre you are being treated in will also be submitting data upon the treatments provided and patient outcomes achieved. This will be regularly checked and monitored against corresponding national and international data provided by the Extracorporeal Life Support Organisation so any deviation can be investigated and, if necessary, improvements made.

Your safety and wellbeing is of primary importance. An ICU can be a dangerous place with a range of potentially hazardous drugs and equipment around. Patients receiving ECMO are at particular risk of infections. Therefore, it is a requirement of this Specification that all Units have a comprehensive infection control service that demonstrates continuing improvement in accordance with current infection control standards.[5]All Units providing critical care must also have an adverse reporting system that identifies any serious events that may threaten the life or welfare or yourself, your family members, other members of the public or members of staff. Every such incident must be investigated so that lessons may be learnt or improvements made.

Post Treatment Support

Your family and, if possible, you must be involved in discussions regarding your ECMO care and treatments. Your recovery may take some time to accomplish and you will require help from a range of different clinical professionals working within a team. Each team member will have specialist knowledge and training in ECMO. Medical consultants and nurses must provide 24 hour cover and other professional staff will be available to help with your recovery during the daytime. Even after your course of ECMO is completed, you will still require a period of time in a critical care unit and it may be necessary to transfer you to a unit closer to home which may or may not be the unit from which you came. If are to transfer to another hospital, it is expected that this will take place within 24 hours of the time that it is decided that you no-longer require ECMO support and are fit to return.

Your subsequent care will vary according to the clinical condition that caused the need for ECMO in the first place. However, most patients who have had a spell in intensive care will need a range of support services for some time after they have left intensive care – sometimes for many months after they have left the hospital. More details may be found in the guidance published by the National Institute for Clinical Excellence on the rehabilitation of patients after critical illness[6]. In addition, the follow-up of ECMO patients by the specialist ECMO centre is good practice. If your general practitioner or your referring hospital believes that you might benefit from ECMO Centre follow up, then this will be provided.

Unfortunately, it is inevitable that some patients will not respond to ECMO support and will not improve. When this happens End of Life services and palliative care may need to be initiated. This must include counselling and bereavement services.

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[5] The Management and Control of Hospital Infection. HSC 2001/02. NHS Executive Controls Assurance Standards.

[6] Rehabilitation after Critical Illness. Clinical Guideline 83. NICE 2009.

NHS England

Clinical Priorities Advisory Group

25th September, 2013

D16 Adult Critical Care Service Specification 2014/15- ECMO service for Severe Respiratory Failure

Purpose of Paper

Advisory Decision Required	Debate / Co-production
X	

The purpose of the paper :

Currently there are five Nationally designated centres which provide ECMO (Extra corporeal membrane oxygenation) for severe refractory respiratory failure for patients aged 16 years and older. These centres are currently providing the service following award of a tender in April 2012. This service falls within the work programme for the Adult Critical Care CRG. The ACC CRG requests adoption of the attached service specification.

The CPAG is asked:

To consider and approve the national service specification for Adult Critical Care: ECMO for severe respiratory failure for full public consultation.

Report Author:	Michele Davis (Accountable Commissioner)

Involvement Thus Far (please indicate with an "X below)

Operations	Finance	Patients and Information	Medical	Nursing	HR	Policy	Commissioning Development
		x	X	x			

Governance Approval

CRG	POC Board	SSOG	CPAG	DCSC
x				

Funding Implications