



Conventional Ventilation or
ECMO for
Severe
Adult
Respiratory Failure

Summary of Economic Evaluation

[ISRCTN47279827](#)

Background to the trial

Approximately 350 adults develop severe, but potentially reversible, respiratory failure in the UK every year. Whilst intensive care of these patients is improving in specialist centres the mortality for the majority of these severely ill patients has changed little in the last 20 years, and is approximately 70%. Extra corporeal membrane oxygenation (ECMO) provides gas exchange whilst the lungs are rested and allowed to recover, thereby reducing the effects of ventilator lung injury, an approach proven to result in improved survival in the NIH ARDS Network study. ECMO is an evidence-based treatment in severe *neonatal* respiratory failure ¹ resulting in improved outcome compared to conventional ventilation. The Glenfield Hospital group has treated over 200 adults with ECMO since 1989. A detailed study of the first 50 patients revealed a hospital mortality of 34% for patients with a mean PaO₂/FIO₂ ratio of 65 mmHg and Murray score of 3.4 ².

Currently, there is no good evidence from randomised controlled trials (RCTs) to compare ECMO against conventional management for important clinical or economic outcomes for adults. The CESAR trial aims to bridge this gap by conducting an RCT where adults with severe, but potentially reversible, respiratory failure are randomised for consideration of ECMO or continuing conventional ventilation and by conducting an economic evaluation alongside the trial.

The trial is being funded by the NHS Executive Research and Development Health Technology Assessment programme and treatment costs are provided by the National Specialist Commissioning Advisory Group (NSCAG) and has ethical approval for all participating centres.

Primary hypotheses

For patients with severe, but potentially reversible, respiratory failure, ECMO:

- (a) Will increase the rate of survival without severe disability by six months post randomisation.
- (b) Will be cost effective from the viewpoints of the NHS and society.

Economic Evaluation

The economic evaluation will be co-ordinated by the Health Economics Group at the University of East Anglia, Norwich and the Sheffield Health Economics Group at the University of Sheffield.

The main objective is to assess the incremental cost-effectiveness of ECMO in terms of additional survival with and without severe disability at 6 months post-randomisation. Incremental cost-effectiveness is estimated as the ratio of differences in cost to differences in chosen outcome between the two treatment options (ECMO and conventional ventilation).

Costs of different treatment options will arise at the initial provision of care and as a consequence of health needs following initial intervention. The economic evaluation will assess and report separately the costs that fall upon all the different agencies such as the NHS, social services and households and will assess cost-effectiveness from the viewpoint of the NHS and society.

Data will be collected within the trial on ICU-specific resource use, other in-patient hospital resource use and ambulance resource use. Use of resources after discharge will be collected through a questionnaire-based patient interview at 6-months following trial entry.

The costs of intensive and high dependency care will be determined using a 'top-down' costing method, namely, the cost block method³. The average daily cost in each recruiting unit will be severity / case-mix adjusted using either the patient's level of care data or by the type of organ system support received. These weights will be produced using level of care and organ system support data collected as part of the Critical Care National Healthcare Resource Group (HRG) Study⁴. The cost of in-patient hospital care following discharge from critical care will be calculated using NHS Reference Costs⁵.

Cost for each item of resource used by each patient will be calculated as the quantity of resource used by that patient multiplied by the unit cost for that item of resource. Unit costs for health and social care will be based on nationally available data⁶.

Total costs for each arm of the trial will be estimated as the summation of the products of quantity and unit costs for each item of service for each patient. This will allow variations in cost within and between randomised groups to be investigated.

Cost-effectiveness analysis will be conducted by combining the above total cost estimates together with clinical outcomes to obtain a cost-effectiveness ratio. A sensitivity analysis will also be conducted to investigate the effects of varying key assumptions in the costing process on the cost-effectiveness analysis results.

Two sub-studies on other aspects of ICU costs are also being planned: (1) a study on the costs of visiting adult ICU patients by family members and relatives and (2) a study on the costs to the NHS of patients who die in hospital.

Finally, the implication of the trial for efficient provision of ECMO services in the UK will be considered. Analysis will be done to assess sensitivity of the cost-effectiveness ratio to transport and local volume of service in the ICU and ECMO units in order to predict the best configuration of ECMO services, if the treatment is found to be effective.

References

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Contacting the Economic Evaluation team:

<p>Professor Miranda Mugford Professor of Health Economics School of Health Policy and Practice University of East Anglia Norwich NR4 7TJ Tel: 01603 593 583 Email: m.mugford@uea.ac.uk</p>	<p>Mrs Mariamma Thalanany Economics Researcher School of Health Policy & Practice University of East Anglia Norwich NR4 7TJ Tel: 01603 591 107 Email: m.thalanany@uea.ac.uk</p>
<p>Miss Clare Hibbert MRC Fellow in Health Services Research ScHARR University of Sheffield Regent Court 30 Regent Street Sheffield S1 4DA Tel: 0114 222 0713 Email: CHibbert1@aol.com</p>	<p>Dr David Edbrooke Consultant in Critical Care Directorate of Critical Care Royal Hallamshire Hospital Glossop Road Sheffield S10 2JF Tel: 0114 271 2405 Email: dedbrooke@aol.com</p>
<p>Miss Lizzie Coates ScHARR University of Sheffield Regent Court 30 Regent Street Sheffield, S1 4DA Tel: 0114 222 0869 Email: lizziecoates2001@yahoo.co.uk</p>	

Further information about the CESAR trial is available from our website
www.cesar-trial.org